INTERNATIONAL SEARCH REPORT

Inter...nal Application No
PCT/GB2005/000223

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/20 A61M5/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 544 234 B1 (GABRIEL JOCHEN) 8 April 2003 (2003-04-08) column 2, line 24 - column 5, line 65; figures 1-19	1-32
Y	WO 03/097133 A (OWEN MUMFORD LIMITED; MARSHALL, JEREMY) 27 November 2003 (2003-11-27) page 4, line 5 - page 7, line 7; figures 1-5	1-32
A	US 5 681 291 A (GALLI ET AL) 28 October 1997 (1997-10-28) column 5, line 4 - column 9, line 52; figures 1-13	1-32

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 June 2005	23/06/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Reinbold, S

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INTERNATIONAL SEARCH REPORT

Inter ... al Application No
PCT/GB2005/000223

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/09186 A (MEDI-JECT CORPORATION; SADOWSKI, PETER, L; DEBOER, DAVID, M; BERMAN, C) 24 February 2000 (2000-02-24) cited in the application the whole document	1-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter al Application No
PCT/GB2005/000223

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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Date
27.09.07

Reference	Application No./Patent No.
P103497EP	05701985.3 - 2310 / 1715903
Applicant/Proprietor: The Medical House Plc	

Decision to grant a European patent pursuant to article 97(2) EPC

Following examination of European patent application No. 05701985.3 a European patent with the title and the supporting documents indicated in the communication pursuant to Rule 51(4) EPC dated 30.04.07 is hereby granted in respect of the designated Contracting States.

Patent No. : 1715903
Date of filing : 24.01.05
Priority claimed : 23.01.04/GBA 0401469
27.01.04/CAA 2455937
28.01.04/USA 767860

Designated Contracting States and Proprietor(s) : AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR
The Medical House Plc
199 Newhall Road
Attercliffe
Sheffield S9 2QJ/GB

This decision will take effect on the date on which the European Patent Bulletin mentions the grant (Art. 97(4) and (5) EPC).

The mention of the grant will be published in European Patent Bulletin 07/43 of 24.10.07.

Examining Division

Reinbold S Skorovs P Valfort C

Europäisches Patentamt • European Patent Office • Office européen des brevets

Registered letter
EPO Form 2006A 07.02 21.09.07

to EPO postal service: 21.09.07

ANMERKUNG ZUR ENTSCHEIDUNG ÜBER DIE ERTEILUNG EINES EUROPÄISCHEN PATENTS (EPA Form 2006)

1. **EPA Informationsbroschüre "Nationales Recht zum EPÜ"**
   Diese Broschüre enthält nützliche Informationen zu den formalen Erfordernissen und den Handlungen, die vor den Patentbehörden der Vertragsstaaten vorzunehmen sind, um Rechte in diesen Staaten zu erlangen. Da diese Handlungen einem ständigen Wandel unterworfen sind, sollte immer nur die neueste Ausgabe der Broschüre benutzt werden. Nachträgliche Informationen werden im Amtsblatt veröffentlicht.

2. **Übersetzung der europäischen Patentschrift nach Artikel 65(1) des Europäischen Patentübereinkommens**
   Sie werden erneut darauf hingewiesen, dass bestimmte Vertragsstaaten nach Artikel 65(1) EPÜ eine Übersetzung der europäischen Patentschrift verlangen; hierauf wird in der Mitteilung gemäss Regel 51(6) verwiesen. **Die Nichteinreichung dieser Übersetzung kann zur Folge haben, dass das Patent in dem betreffenden Staat/in den betreffenden Staaten als von Anfang an nicht eingetreten gilt.** Weitere Einzelheiten entnehmen Sie bitte der oben genannten Broschüre.

3. **Zahlung von Jahresgebühren für europäische Patente**
   Nach Artikel 141 EPÜ können "nationale" Jahresgebühren für das europäische Patent für die Jahre erhoben werden, die an das Jahr anschliessen, in dem der Hinweis auf die Erteilung des europäischen Patents im "Europäischen Patentblatt" bekanntgemacht wird. Weitere Einzelheiten entnehmen Sie bitte der oben genannten Broschüre.

NOTE RELATING TO THE DECISION TO GRANT A EUROPEAN PATENT (EPO Form 2006)

1. **EPO Information Brochure "National law relating to the EPC".**
   This brochure provides useful information regarding formal requirements and the steps to be taken before the patent authorities of the Contracting States in order to acquire rights in those states. Since the necessary steps are subject to change the latest edition of the brochure should always be used. Subsequent information is published in the Official Journal.

2. **Translation of the European patent specification under Article 65(1) of the European Patent Convention**
   Your attention is again drawn to the requirements regarding translation of the European patent specification laid down by a number of Contracting States under Article 65(1) EPC, to which reference is made in the communication under Rule 51(6). **Failure to supply such translation(s) may result in the patent being deemed to be void "ab initio" in the State(s) in question.** For further details you are recommended to consult the above-mentioned brochure.

3. **Payment of renewal fees for European patents**
   Under Article 141 EPC "national" renewal fees in respect of a European patent may be imposed for the years which follow that in which the mention of the grant of the European patent is published in the "European Patent Bulletin". For further details you are recommended to consult the above-mentioned brochure.

REMARQUE RELATIVE A LA DECISION DE DELIVRANCE D'UN BREVET EUROPEEN (OEB Form 2006)

1. **Brochure d'information de l'OEB "Droit national relatif à la CBE"**
   Cette brochure fournit d'utiles renseignements sur les conditions de forme requises et sur les actes à accomplir auprès des offices de brevet des Etats contractants aux fins d'obtenir des droits dans les Etats contractants. Etant donné que les actes indispensables sont susceptibles de modifications, il serait bon de toujours consulter la dernière édition de la brochure. Toute information ultérieure est publiée au Journal Officiel.

2. **Traduction du fascicule du brevet européen en vertu de l'article 65(1) de la Convention sur le brevet européen**
   Votre attention est de nouveau attirée sur l'obligation faite par certains Etats contractants, en vertu de l'article 65(1) CBE, de fournir une traduction du fascicule du brevet européen, à laquelle il est fait référence dans la notification établie conformément à la règle 51(6). **Si la(les) traduction(s) n'est(ne sont) pas fournie(s), le brevet européen peut, dès l'origine, être réputé sans effet dans cet(ces) Etat(s).**
   Pour plus de détails, nous vous renvoyons à la brochure susmentionnée.

3. **Paiement des taxes annuelles pour le brevet européen**
   Conformément à l'article 141 CBE, les taxes annuelles "nationales" dues au titre du brevet européen peuvent être percues pour les années suivant celle au cours de laquelle la mention de la délivrance du brevet européen est publiée au "Bulletin européen des brevets". Pour plus de détails, nous vous renvoyons à la brochure susmentionnée.

EPA/EPO/OEB FORM 2006R 06.95 05701985.3 (21.09.07)

HGF
Harrison Goddard Foote
Patent and Trade Mark
Attorneys

European Patent Office
80298 MUNICH
Germany

21 August 2007

Your ref:
Our ref: MJA/P103497EP

Dear Sirs

European Patent Application No 05701985.3
Auto Safety Injector
The Medical House plc

This letter and enclosures are in response to the Communication under Rule 51(4) EPC dated 30 April 2007.

The text accompanying the above communication is hereby approved. Enclosed herewith are translations of the agreed claims into French and German, together with a fee voucher in respect of the fees for grant and printing of the European patent.

The relevant fees should be debited from our deposit account number 28050228. The EPO is hereby authorised to debit or credit any under or over payment in the fees specified in the attached fee voucher to the above referenced deposit account.

The applicant also requests that you provide a paper copy of the specification together with the certificate for the European patent.

Please return EPO Form 1037, enclosed herewith, as confirmation of receipt.

Yours faithfully

Zur Kasse
A-€992,-

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REVENDICATIONS

1 - Dispositif d'injection comprenant un boîtier externe (30) apte à recevoir :

- un cylindre pour contenir un volume d'un médicament ;
- une aiguille (10) à l'une des extrémités du cylindre, l'aiguille et le cylindre étant tels qu'au moins une partie de l'aiguille est axialement déplaçable dans et hors dudit boîtier externe (30) mais est sollicitée pour être normalement entièrement à l'intérieur dudit boîtier ; et
- un piston (8), déplaçable axialement à l'intérieur du cylindre,

le dispositif d'injection comprenant en outre :

- un boîtier interne (7) dans une position intermédiaire entre le boîtier externe et les cylindre et piston ; et
- une source d'énergie (1; 40) en communication avec ledit boîtier interne (7),

le dispositif étant déplaçable entre deux positions, à savoir :

- une première position dans laquelle le dispositif agit sur le cylindre de telle sorte qu'en utilisation, les piston et cylindre sont déplaçables axialement de façon à déplacer au moins une partie de ladite aiguille hors du boîtier externe ; et
- une seconde position dans laquelle le dispositif agit sur le piston mais non sur le cylindre de telle sorte qu'en utilisation, ledit piston est déplaçable axialement dans ledit cylindre de façon à expulser le médicament à travers l'aiguille ;

caractérisé par le fait que ledit boîtier interne (7) est déplaçable par la source d'énergie entre trois positions, à savoir :

- ladite première position dans laquelle le boîtier interne a une ou plusieurs pattes flexibles radialement (7B) en communication avec le cylindre de telle sorte qu'en

utilisation, les piston et cylindre sont déplaçables axialement de façon à déplacer au moins une partie de ladite aiguille hors du boîtier externe ;

- ladite seconde position dans laquelle le boîtier interne a une ou plusieurs pattes flexibles radialement (7A) en communication avec le piston mais non avec le cylindre de telle sorte qu'en utilisation, ledit piston est déplaçable axialement dans ledit cylindre de façon à expulser le médicament à travers l'aiguille ; et
- une troisième position dans laquelle lesdites pattes flexibles radialement (7A, 7B) sur le boîtier interne ne sont en communication ni avec le piston ni avec le cylindre de telle sorte qu'en utilisation, les piston et cylindre sont aptes à se rétracter afin de rétracter l'aiguille dans le boîtier externe.

2 - Dispositif d'injection selon la revendication 1, à l'intérieur duquel sont situés :

- ledit cylindre pour contenir un volume d'un médicament ;
- ladite aiguille (10) à l'une des extrémités du cylindre ; et
- ledit piston (8), déplaçable axialement à l'intérieur du cylindre.

3 - Dispositif d'injection selon la revendication 1 ou la revendication 2, comprenant en outre un boîtier de ressort (41) dans une position intermédiaire entre le boîtier externe (30) et le boîtier interne (7).

4 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel une ou plusieurs desdites pattes sont situées à l'extrémité d'un bras élastiquement flexible.

5 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel une ou plusieurs desdites pattes sont situées à l'extrémité arrière du boîtier interne et sont déplaçables radialement dans et hors de communication avec le piston.

6 - Dispositif d'injection selon l'une quelconque des revendications 3 à 5, dans lequel lesdites pattes sont

sollicitées radialement vers l'intérieur en communication avec ledit piston, de préférence par communication avec ledit boîtier de ressort.

7 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel lesdites pattes sont maintenues dans leur condition relaxée, avant l'amorçage d'une injection.

8 - Dispositif d'injection selon l'une quelconque des revendications 3 à 7, dans lequel chaque patte arrière est déplaçable hors de communication avec le piston lorsqu'elle est alignée avec une cavité correspondante dans le boîtier de ressort.

9 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel chaque patte arrière est sensiblement en forme de T.

10 - Dispositif d'injection selon l'une quelconque des revendications 1 à 4, dans lequel une ou plusieurs desdites pattes sont situées à l'extrémité avant du boîtier interne et sont déplaçables radialement dans et hors de communication avec le cylindre.

11 - Dispositif d'injection selon la revendication 10, dans lequel lesdites pattes avant sont sollicitées radialement vers l'intérieur en communication avec ledit cylindre, de préférence par communication avec ledit boîtier de ressort.

12 - Dispositif d'injection selon la revendication 10 ou la revendication 11, dans lequel lesdites pattes avant sont maintenues dans leur condition relaxée, avant l'amorçage d'une injection.

13 - Dispositif d'injection selon l'une quelconque des revendications 10 à 12, dans lequel chaque patte avant est déplaçable hors de communication avec le cylindre lorsqu'elle est alignée avec une cavité correspondante dans le boîtier de ressort.

14 - Dispositif d'injection selon l'une quelconque des revendications 10 à 13, dans lequel chaque patte avant est sensiblement en forme de L.

15 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel ladite source d'énergie est un gaz comprimé.

16 - Dispositif d'injection selon l'une quelconque des revendications 1 à 14, dans lequel ladite source d'énergie est un ressort.

17 - Dispositif d'injection selon l'une quelconque des revendications précédentes, comprenant en outre un moyen pour permettre au boîtier interne de se déplacer axialement seulement vers l'avant par rapport au boîtier externe.

18 - Dispositif d'injection selon la revendication 17, dans lequel ledit moyen est un arrangement de dentelures, de barbes, de dents de rochet ou similaires dans une position intermédiaire entre les boîtiers.

19 - Dispositif d'injection selon l'une quelconque des revendications précédentes, comprenant en outre un moyen de guidage pour guider, en utilisation, le mouvement axial relatif des boîtiers de ressort et externe, le moyen de guidage comprenant de préférence une ou plusieurs saillies sur ledit boîtier de ressort, lesquelles, en utilisation, coopèrent avec des cavités correspondantes sur une surface intérieure dudit boîtier externe.

20 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel ladite aiguille est sollicitée pour être normalement entièrement à l'intérieur dudit boîtier au moyen d'un ressort dans une position intermédiaire entre le cylindre et les boîtiers externe et/ou de ressort.

21 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel l'aiguille est apte à être retirée dudit dispositif.

22 - Dispositif d'injection selon l'une quelconque des revendications précédentes, dans lequel

ladite aiguille, ledit cylindre et ledit piston sont aptes à être retirés dudit dispositif.

23 - Dispositif d'injection selon l'une quelconque des revendications précédentes, comprenant en outre un étui protecteur d'aiguille apte à retiré, qui protège l'aiguille pendant le stockage avant l'utilisation.

24 - Dispositif d'injection selon la revendication 23, dans lequel ledit étui protecteur d'aiguille comprend un moyen pour tirer une gaine protectrice en caoutchouc ou similaire à partir de ladite aiguille lorsque ledit étui protecteur d'aiguille est retiré du dispositif.

25 - Dispositif d'injection selon la revendication 24, dans lequel ledit moyen de traction comprend un rivet flottant dans une position intermédiaire entre l'étui protecteur d'aiguille et la gaine protectrice en caoutchouc ou similaire, ce par quoi des forces de torsion appliquées audit étui protecteur d'aiguille sont sensiblement empêchées d'être transmises à ladite gaine en caoutchouc ou similaire.

26 - Dispositif d'injection selon l'une quelconque des revendications 23 à 25, dans lequel la présence dudit étui protecteur d'aiguille sur ledit dispositif sert de verrou de sécurité, empêchant sensiblement un mouvement vers l'avant relatif dudit boîtier externe.

27 - Dispositif d'injection selon l'une quelconque des revendications précédentes, comprenant en outre une fenêtre d'observation dans ledit cylindre alignée avec une fenêtre d'observation dans ledit boîtier externe de telle sorte que ledit médicament peut être observé par un utilisateur avant qu'une injection n'ait lieu.

28 - Dispositif d'injection selon la revendication 27, dans lequel, en utilisation pendant une injection, ledit boîtier interne se déplace dans une position intermédiaire entre ladite fenêtre d'observation

dans le boîtier externe et ledit cylindre de façon à cacher la fenêtre dans le cylindre à la vue de l'utilisateur.

29 - Dispositif d'injection selon l'une quelconque des revendications précédentes, comprenant en outre un moyen pour émettre une indication audible et/ou physique à un utilisateur selon laquelle l'injection est terminée.

Ansprüche

1. Injektionsvorrichtung mit einem äußeren Gehäuse (30), das zur Aufnahme des Folgenden ausgestaltet ist:
eines Spritzenkörpers zum Aufnehmen eines Volumens eines Medikaments,
einer Kanüle (10) an einem Ende des Spritzenkörpers, wobei die Kanüle und der Spritzenkörper so beschaffen sind, dass wenigstens ein Teil der Kanüle axial in das äußere Gehäuse und aus dem äußeren Gehäuse (30) beweglich ist, aber so vorgespannt ist, dass sie normalerweise vollständig innerhalb des Gehäuses liegt, und
eines Kolbens (8), der in dem Spritzenkörper axial beweglich ist,
wobei die Injektionsvorrichtung weiter aufweist:
ein inneres Gehäuse (7) zwischen äußerem Gehäuse und Spritzenkörper und Kolben, und
eine Energiequelle (1; 40) in Verbindung mit dem inneren Gehäuse (7),
wobei die Vorrichtung zwischen zwei Stellungen beweglich ist, nämlich
einer ersten Stellung, in der die Vorrichtung auf den Kolben so einwirkt, dass bei Benutzung der Kolben und der Spritzenkörper axial beweglich sind, um so wenigstens einen Teil der Kanüle aus dem äußeren Gehäuse heraus zu bewegen, und
einer zweiten Stellung, in der die Vorrichtung auf den Kolben einwirkt, aber nicht auf den Spritzenkörper, so dass bei Benutzung der Kolben axial in den Spritzenkörper hinein beweglich ist, um so Medikament durch die Kanüle auszustoßen,
dadurch gekennzeichnet, dass das innere Gehäuse (7) durch die Energiequelle zwischen drei Stellungen beweglich ist, nämlich

der ersten Stellung, in der das innere Gehäuse einen oder mehrere radial flexible Fortsätze (7B) in Verbindung mit dem Spritzenkörper hat, so dass bei Benutzung der Kolben und der Spritzenkörper axial beweglich sind, um so wenigstens einen Teil der Kanüle aus dem äußeren Gehäuse heraus zu bewegen,
der zweiten Stellung, in der das innere Gehäuse einen oder mehrere radial flexible Fortsätze (7A) in Verbindung mit dem Kolben, aber nicht mit dem Spritzenkörper hat, so dass bei Benutzung der Kolben axial in den Spritzenkörper beweglich ist, um so Medikament durch die Kanüle auszustoßen, und
einer dritten Stellung, in der die radial flexiblen Fortsätze (7A, 7B) an dem inneren Gehäuse weder in Verbindung mit dem Kolben noch mit dem Spritzenkörper sind, so dass bei Benutzung der Kolben und der Spritzenkörper dazu in der Lage sind, sich zurückzuziehen, um die Kanüle in das äußere Gehäuse hinein zurückzuziehen.

2. Injektionsvorrichtung nach Anspruch 1, innerhalb der angeordnet sind:
der Spritzenkörper zum Aufnehmen eines Volumens eines Medikaments,
die Kanüle (10) an einem Ende des Spritzenkörpers, und
der Kolben (8), der axial beweglich innerhalb des Spritzenkörpers ist.

3. Injektionsvorrichtung nach Anspruch 1 oder Anspruch 2, die weiter ein Federgehäuse (41) zwischen dem äußeren Gehäuse (30) und dem inneren Gehäuse (7) aufweist.

4. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei einer oder mehrere der Fortsätze am Ende eines elastisch flexiblen Stegs angeordnet sind.

5. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei einer oder mehrere der Fortsätze am hinteren Ende des inneren Gehäuses angeordnet sind und radial in und außer Verbindung mit dem Kolben beweglich sind.

6. Injektionsvorrichtung nach einem der Ansprüche 3 bis 5, wobei die Fortsätze mit einer Vorspannung radial nach innen in Verbindung mit dem Kolben beaufschlagt sind, vorzugsweise durch Verbindung mit dem Federgehäuse.

7. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei die Fortsätze in ihren entspannten Zustand in Ruhestellung gebracht sind, bevor eine Injektion eingeleitet wird.

8. Injektionsvorrichtung nach einem der Ansprüche 3 bis 7, wobei jeder hintere Fortsatz in und außer Verbindung mit dem Kolben beweglich ist, wenn er mit einer entsprechenden Vertiefung in dem Federgehäuse ausgerichtet ist.

9. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei jeder hintere Fortsatz im Wesentlichen T-förmig ist.

10. Injektionsvorrichtung nach einem der Ansprüche 1 bis 4, wobei einer oder mehrere der Fortsätze am vorderen Ende des inneren Gehäuses angeordnet sind und radial in und außer Verbindung mit dem Kolben beweglich sind.

11. Injektionsvorrichtung nach Anspruch 10, wobei die vorderen Fortsätze radial nach innen in Verbindung mit dem Kolben vorgespannt sind, vorzugsweise durch Verbindung mit dem Federgehäuse.

12. Injektionsvorrichtung nach Anspruch 10 oder Anspruch 11, wobei die vorderen Fortsätze in ihren entspannten Zustand in Ruhestellung gebracht sind, bevor eine Injektion eingeleitet wird.

13. Injektionsvorrichtung nach einem der Ansprüche 10 bis 12, wobei jeder vordere Fortsatz außer Verbindung mit dem Kolben beweglich ist, wenn er mit einer entsprechenden Vertiefung in dem Federgehäuse ausgerichtet ist.

14. Injektionsvorrichtung nach einem der Ansprüche 10 bis 13, wobei jeder vordere Fortsatz im Wesentlichen L-förmig ist.

15. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei die Energiequelle ein komprimiertes Gas ist.

16. Injektionsvorrichtung nach einem der Ansprüche 1 bis 14, wobei die Energiequelle eine Feder ist.

17. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, die weiter Mittel umfasst, die dem inneren Gehäuse eine axiale Bewegung nur vorwärts in Bezug auf das äußere Gehäuse gestatten.

18. Injektionsvorrichtung nach Anspruch 17, wobei die Mittel eine Anordnung von Rippen, Widerhaken, Sperrklinken oder dergleichen zwischen den Gehäusen sind.

19. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, die weiter eine Führungseinrichtung aufweist, um bei Benutzung die relative axiale Bewegung von Feder- und äußerem Gehäuse zu führen, wobei die Führungseinrichtung vorzugsweise einen oder mehrere Fortsätze an dem Federgehäuse umfasst, der oder die bei Benutzung mit entsprechen-

den Vertiefungen an einer Innenfläche des äußeren Gehäuses zusammenwirken.

20. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei die Kanüle mittels einer Feder zwischen dem Kolben und dem äußeren und/oder Federgehäuse in eine normalerweise vollständig innerhalb des Gehäuses liegende Stellung vorgespannt ist.

21. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei die Kanüle von der Vorrichtung abnehmbar ist.

22. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, wobei die Kanüle, der Spritzenkörper und der Kolben aus der Vorrichtung entfernbar sind.

23. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, die weiter eine abnehmbare Kanülenkappe aufweist, die die Kanüle während der Aufbewahrung vor ihrer Benutzung schützt.

24. Injektionsvorrichtung nach Anspruch 23, wobei die Kanülenkappe Mittel aufweist, um eine Schutzgummihülle oder dergleichen von der Kanüle abzuziehen, wenn die Kanülenkappe von der Vorrichtung abgenommen wird.

25. Injektionsvorrichtung nach Anspruch 24, wobei die Abziehmittel einen beweglichen Bolzen zwischen der Kanülenkappe und der Schutzgummihülle oder dergleichen umfassen, wodurch auf die Kanülenkappe ausgeübte Drehkräfte im Wesentlichen an der Übertragung auf die Gummihülle oder dergleichen gehindert werden.

26. Injektionsvorrichtung nach einem der Ansprüche 23 bis 25, wobei das Vorhandensein der Kanülenkappe an der Vorrichtung als ein Sicherheitsverschluss dient, der im Wesentlichen eine relative Vorwärtsbewegung des äußeren Gehäuses verhindert.

27. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, die weiter ein Sichtfenster in dem Spritzenkörper ausgerichtet mit einem Sichtfenster in dem äußeren Gehäuse aufweist, so dass das Medikament von einem Benutzer betrachtet werden kann, bevor eine Injektion stattfindet.

28. Injektionsvorrichtung nach Anspruch 27, wobei bei der Anwendung während einer Injektion das innere Gehäuse sich zwischen das Sichtfenster in dem äußeren Gehäuse und in dem Spritzenkörper bewegt, um so das Fenster in dem Spritzenkörper für den Betrachter unsichtbar zu machen.

29. Injektionsvorrichtung nach einem der vorhergehenden Ansprüche, die weiter eine Einrichtung zur Aussendung einer akustischen und/oder physikalischen Anzeige für den Benutzer, dass die Injektion abgeschlossen ist, aufweist.

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Stainthorpe, Vanessa Juliet
Harrison Goddard Foote,
Fountain Precinct
Balm Green
Sheffield S1 2JA
ROYAUME-UNI

Application No.	Ref.	Date
05 701 985.3 - 2310	P103497EP	30.04.2007
Applicant: The Medical House Plc		

Communication under Rule 51(4) EPC

You are informed that the Examining Division intends to grant a European patent on the basis of the above application with the text and drawings as indicated below:

In the text for the Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

Description, Pages

9-26	as published
1-7	filed with telefax on 10.11.2006

Claims, Numbers

2-29	filed with telefax on 10.11.2006
1	filed with telefax on 13.03.2007

Drawings, Sheets

1/27-27/27	as published

A copy of relevant documents is enclosed

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated Contracting States, the registered name of the applicant and the bibliographic data are shown on the attached EPO Form 2056.

You are requested within a **non-extendable** period of four months of notification of this communication

Registered Letter
EPO Form 2004 01.06CSX

1. to file 1 set of translations of the claim(s) in the two other EPO official languages;

		EUR
2a. to pay the fee for grant including the fee for printing up to and including 35 pages;	Reference 007	750.00
2b. to pay the printing fee for the 36th and each additional page; number of pages: 22	Reference 008	242.00
3. to pay the additional claim fee(s) (Rule 51(7) EPC); number of claims fees payable:	Reference 016	0.00
	Total amount	992.00

Concerning the possibility of a request for accelerated grant pursuant to Article 97(6) EPC, reference is made to OJ EPO 2001, 459.

If you do not approve the text intended for grant but wish to request amendments or corrections, the procedure described in Rule 51(5) EPC is to be followed.

If this communication is based upon an auxiliary request, and you reply within the time limit set that you maintain the main or a higher ranking request which is not allowable, the application will be refused (Article 97(1) EPC, see also Legal Advice 15/05 (rev. 02), OJ 6/2005, 357).

If the enclosed claims contain amendments proposed by the Examining Division, and you reply within the time limit set that you cannot accept these amendments, refusal of the application under Article 97(1) EPC would result in the case that agreement cannot be reached on the text for grant.

In all cases except those of the previous two paragraphs, if the grant, printing or claims fees are not paid, or the translations not filed, in due time, the European patent application will be deemed to be withdrawn (Rule 51(8) EPC).

For all payments you are requested to use EPO Form 1010 or to refer to the relevant reference number.

After publication, the European patent specification can be downloaded free of charge from the EPO publication server https://publications.european-patent-office.org or ordered only from the Vienna sub-office upon payment of a fee (OJ EPO 2005, 126).

Upon request in writing each proprietor will receive the certificate for the European patent **together with one copy** of the patent specification only if the request is filed within the time limit of Rule 51(4) EPC. If such request has been previously filed, it has to be confirmed within the time limit of Rule 51(4) EPC. The requested copy is free of charge. If the request is filed after expiry of the Rule 51(4) EPC time limit, the certificate will be delivered without a copy of the patent specification.

Translation of the priority document(s)

If the translation of the priority document(s), as required by Article 88(1) EPC, or the declaration according to Rule 38(5) EPC has not yet been filed, Form 2530 will be despatched separately. The translation is to be filed within the above mentioned time limit (Rule 38(5) EPC).

Note on payment of renewal fees

If a renewal fee falls due between notification of the present communication and the proposed date of publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (Rule 51(9) EPC).

Under Article 86(4) EPC, renewal fees are payable to the European Patent Office until the year in which the mention of the grant of the European patent is published.

Filing of translations in the Contracting States

Pursuant to Article 65(1) EPC the following Contracting States require a translation of the specification of the European patent in their/one of their official language(s) (Rule 51(10) EPC), **insofar** this specification will not be published in their/one of their official language(s)

- within **three** months of publication of the mention of such decision:

AT	AUSTRIA	GR	GREECE
BE	BELGIUM	HU	HUNGARY
BG	BULGARIA	IS	ICELAND
CH	SWITZERLAND / LIECHTENSTEIN	IT	ITALY
CY	CYPRUS	LT	LITHUANIA
CZ	CZECH REPUBLIC	NL	NETHERLANDS
DE	GERMANY	PL	POLAND
DK	DENMARK	PT	PORTUGAL
EE	ESTONIA	RO	ROMANIA
ES	SPAIN	SE	SWEDEN
FI	FINLAND	SI	SLOVENIA
FR	FRANCE	SK	SLOVAKIA
GB	UNITED KINGDOM	TR	TURKEY

- within **six** months of publication of the mention of such decision:

IE IRELAND

The date on which the European Patent Bulletin publishes the mention of the grant of the European patent will be indicated in the decision on the grant of the European patent (EPO Form 2006).

In case of a valid extension the following Extension States require a translation of the **claims** in their official language within **three** months after publication of the mention of the grant of the European patent:

AL	ALBANIA	LV	LATVIA
BA	BOSNIA-HERZEGOVINA	MK	MACEDONIA
HR	CROATIA *	YU	SERBIA AND MONTENEGRO

* requires translation of the specification

The translation must be filed with the national Patent Offices of the Contracting or Extension States in accordance with the provisions applying thereto in the State concerned. Further details (e.g. appointment of a national representative or indication of an address for service within the country) are given in the EPO information brochure "National law relating to the EPC", and in the supplementary information published in the Official Journal of the EPO, or available on the EPO website.

Failure to supply such translation to the Contracting and Extension States in time and in accordance with the requirements may result in the patent being deemed to be void ab initio in the State concerned.

Note to users of the automatic debiting procedure

Unless the EPO receives prior instructions to the contrary, the fee(s) will be debited on the last day of the period of payment. For further details see the Arrangements for the automatic debiting procedure (see Supplement to OJ EPO 2, 2002).

Examining Division:

Chairman:	Valfort, Cyril
2nd Examiner:	Skorovs, Peteris
1st Examiner:	Reinbold, Sylvie

Eich, Martine
For the Examining Division
Tel. No.: +49 89 2399 - 7578

Enclosure(s): Form 2056
57 Copies of the relevant documents

Registered Letter
EPO Form 2004 01.06CSX

Annex to EPO Form 2004, Communication under Rule 51(4) EPC

Bibliographical data of European patent application No. 05 701 985.3

For the intended grant of a European patent, the bibliographical data are set out below, for information:

Title of invention:	- INJEKTIONSVORRICHTUNG - INJECTION DEVICE - DISPOSITIF D'INJECTION
Classification:	INV. A61M5/20 A61M5/30
Date of filing:	24.01.2005
Priority claimed:	GB / 23.01.2004 / GBA0401469 CA / 27.01.2004 / CAA2455937 US / 28.01.2004 / USA767860
Contracting States* for which fees have been paid:	AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR
Extension States* for which fees have been paid:	AL BA HR LV MK YU
Applicant(s):**	The Medical House Plc 199 Newhall Road Attercliffe Sheffield S9 2QJ GB
Inventor(s):	STAMP, Kevin 57 Greenhead Gardens, Chapeltown Sheffield S35 1AR GB

*) In case the time limits pursuant to Article 79(2) and Rule 85a EPC have not yet expired, **all Contracting States/Extension States** have been mentioned.

**) In case two or more applicants have designated different Contracting States, this is indicated here.

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Primary Examiner (substantive examination) +49 89 2399-7918

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Application No.	Ref.	Date
05 701 985.3 - 2310	P103497EP	02.04.2007
Applicant: The Medical House Plc		

Result of consultation

A copy of the result of consultation of 12.03.2007 is enclosed for your information.

Reinbold, Sylvie
For the Examining Division

Enclosure(s): Copy of result of consultation (Form 2036)

Europäisches Patentamt
GD2

European Patent Office
DG2

Office européen des brevets
DG2

Application No. : 05 701 985.3

Consultation by telephone with the applicant / representative

Despatch for information

Participants

Applicant:	The Medical House Plc
Representative:	Vanessa Stainthorpe
Member(s) of the Examining Division:	Reinbold, Sylvie

Result of consultation

The two part form of claim 1 was discussed.

12.03.2007
Date

Reinbold, Sylvie
Examiner

HGF
Harrison Goddard Foote
Patent and Trade Mark
Attorneys

European Patent Office
Erhardtstrasse 27
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Germany

By Post and Fax: 004989 23994465

FAXED

26 March 2007

Your ref:
Our ref: VJS/AVK/P103497EP

Dear Sirs

European Patent Application No 05701985.3
Injection Device
The Medical House plc

I would be grateful if you could inform me when we could expect to receive the Communication under 51(4) in connection with the above mentioned application. In accordance with the PACE request filed 27 September 2006, the applicant seeks grant as soon as possible.

Two copies of EPO Form 1037 are enclosed, and I should be grateful if you could stamp one of these and return it to us immediately as acknowledgement of receipt of this letter.

Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote

Enc

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Germany

By Post and Fax: 004989 23994465

26 March 2007

Your ref:
Our ref: VJS/AVK/P103497EP

Dear Sirs

European Patent Application No 05701985.3
Injection Device
The Medical House plc

I would be grateful if you could inform me when we could expect to receive the Communication under 51(4) in connection with the above mentioned application. In accordance with the PACE request filed 27 September 2006, the applicant seeks grant as soon as possible.

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Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote

Enc

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Fax (+49-89) 259 01-840

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Harrison Goddard Foote
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SHEFFIELD, S1 2JA
GB

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Bestätigung[2] über den Eingang nachgereichter Unterlagen für Patentanmeldungen/Patente beim Europäischen Patentamt

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	Anmeldenummer/Patentnummer Application Number/Patent Number Numéro de la demande/numéro du brevet	Ihr Zeichen Your reference Votre référence	ggfs. Art und Datum der Unterlagen[3] Nature and date of items (optional)[3] Nature et date des pièces (facultatif)[3]
1.	05701985.3	R103497EP	Letter dated 26/3/07
2.			
3.			
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Harrison Goddard Foote
Fountain Precinct
Balm Green
SHEFFIELD, S1 2JA
GB

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Eingereichte Unterlagen / Items filed / Pièces envoyées

Anmeldenummer/Patentnummer Application Number/Patent Number Numéro de la demande/numéro du brevet		Ihr Zeichen Your reference Votre référence	ggfs. Art und Datum der Unterlagen[3] Nature and date of items (optional)[3] Nature et date des pièces (facultatif)[3]
1.	05701985.3	P103497EP	Letter dated 26/3/07
2.			
3.			
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HGF
Harrison Goddard Foote
Patent and Trade Mark
Attorneys

For The Attention of Ms Sylvie Reinbold

EPO - Munich
21
17. März 2007

European Patent Office
Erhardtstrasse 27
D-80298 MUNICH
Germany

12 March 2007

Your ref:
Our ref: VJS/AMG/P103497EP

By Fax & 0049 89 2399 4465
Post:
Sender: Vanessa Stainthorpe
Pages: 6 inc this page

Dear Sirs

European Patent Application No 05701985.3
Auto Safety Injector
The Medical House plc

With reference to my telephone and email correspondence with Examiner Reinbold today, we are filing herewith replacement page 25 of the claims in which claim 1 has been amended to improve the two-part form. A marked-up copy of the replacement page is also enclosed for the Examiner's reference.

The deletion of any subject matter from the present application should not be construed as abandonment of that subject matter and is not without prejudice to its reinstatement or to filing a divisional application for that subject matter.

The examiner is invited to contact the undersigned if any point remains outstanding that can be usefully resolved by telephone or email.

Oral proceedings are requested if the examiner contemplates refusing the application.

Fountain Precinct, Balm Green
Sheffield S1 2JA UK
Tel: +44(0) 114 274 3700
Fax: +44(0) 114 273 0312
Email: vstainthorpe@hgf.com

Also enclosed are two copies of EPO Form 1037, and I should be grateful if you would stamp and return one of these to me immediately, as an acknowledgement of receipt of this letter and its enclosures.

Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote
Association No: 145

CLAIMS

1. An injection device comprising an outer housing (30) adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7), ~~characterised in that~~

the device being moveable between two positions, namely

a first position in which the device acts on the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing; and

a second position in which the device acts on the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle;

characterised in that said inner housing (7) is moveable by the energy source between three positions, namely

~~a~~ said first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

~~a~~ said second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

CLAIMS

1. An injection device comprising an outer housing (30) adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7),

the device being moveable between two positions, namely

a first position in which the device acts on the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing; and

a second position in which the device acts on the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle;

characterised in that said inner housing (7) is moveable by the energy source between three positions, namely

said first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

said second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

HGF
Harrison Goddard Foote
Patent and Trade Mark
Attorneys

For The Attention of Ms Sylvie Reinbold

European Patent Office
Erhardtstrasse 27
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Germany

12 March 2007

Your ref:
Our ref: VJS/AMG/P103497EP

By Fax & 0049 89 2399 4465
Post:
Sender: Vanessa Stainthorpe
Pages: 6 inc this page

Dear Sirs

European Patent Application No 05701985.3
Auto Safety Injector
The Medical House plc

With reference to my telephone and email correspondence with Examiner Reinbold today, we are filing herewith replacement page 25 of the claims in which claim 1 has been amended to improve the two-part form. A marked-up copy of the replacement page is also enclosed for the Examiner's reference.

The deletion of any subject matter from the present application should not be construed as abandonment of that subject matter and is not without prejudice to its reinstatement or to filing a divisional application for that subject matter.

The examiner is invited to contact the undersigned if any point remains outstanding that can be usefully resolved by telephone or email.

Oral proceedings are requested if the examiner contemplates refusing the application.

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Also enclosed are two copies of EPO Form 1037, and I should be grateful if you would stamp and return one of these to me immediately, as an acknowledgement of receipt of this letter and its enclosures.

Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote
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41

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1.	05701985.3	P103497EP	Letter dated 12 March 2007
2.			Replacement page 25
3.			
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4-1

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Eingereichte Unterlagen | **Items filed** | **Pièces envoyées**

	Anmeldenummer/Patentnummer Application Number/Patent Number Numéro de la demande/numéro du brevet	Ihr Zeichen Your reference Votre référence	ggfs. Art und Datum der Unterlagen [3] Nature and date of items (optional) [3] Nature et date des pièces (facultatif) [3]
1.	05701985.3	P103497EP	Letter dated 12 March 2007
2.			Replacement page 25
3.			
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CLAIMS

1. An injection device comprising an outer housing (30) adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7), ~~characterised in that~~

the device being moveable between two positions, namely

a first position in which the device acts on the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing; and

a second position in which the device acts on the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle;

characterised in that said inner housing (7) is moveable by the energy source between three positions, namely

~~a~~ said first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

~~a~~ said second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

CLAIMS

1. An injection device comprising an outer housing (30) adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7),

the device being moveable between two positions, namely

a first position in which the device acts on the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing; and

a second position in which the device acts on the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle;

characterised in that said inner housing (7) is moveable by the energy source between three positions, namely

said first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

said second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

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14. Nov. 2006

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FAXED

10 November 2006

Your ref: REINBOLD, Sylvie
Our ref: VJS/P103497EP

By Fax: 0049 89 2399 4465
Sender: Vanessa Stainthorpe
Pages: 30 inc this page

Dear Sirs

European Patent Application No 05701985.3
Auto Safety Injector
The Medical House plc

We are writing in response to your communication pursuant to Article 96(2) EPC dated 30 October 2006. A PACE Request was filed 27.09.2006 and we respectfully request that this response is handled as quickly as possible.

With this letter we are filing the following replacement pages, amended in light of the examiner's comments:

Description: pages 2-7 (previous page 8 should be removed and the remaining pages renumbered accordingly)
Claims: Claims 1-29

A further copy of the relevant pages is enclosed on which the amendments have been indicated for the examiner's reference.

Clarity – Article 84 EPC

The examiner objected to the three independent claims 1, 29 and 30. Whilst the applicant does not believe there to be a lack of clarity, in the interest of expedient prosecution, claim 29 has been deleted. Claim 30 has been recast as the main claim, with former claim 1 dependent thereon, so that there now is only one independent claim in this application. Basis for making claim 30 be the main claim with the other claims dependent thereon is found in former claim 31, which has also now been deleted.

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Other Matters

The paragraph numbering below corresponds with the paragraph numbering in the examiner's communication.

3. Reference signs in parentheses have been added to new claim 1 (former claim 30).

4. Former claim 1 was indeed already in two-part form, but this issue is no longer relevant given the amendment to this claim, which is now dependent claim 2. New claim 1 (former claim 30) is also already in two-part form.

5. Document D1 was already identified and discussed on page 2 of the description filed upon entry into the European regional phase. Document D2 is identified and discussed on replacement page 2 filed herewith. D2, namely WO03/097133 (Owen Mumford) discloses an injection device with a retractable needle but with the driving force applied to the liquid inside the syringe, using the liquid's incompressible nature to cause the needle to move forward. A relatively complex arrangement is required for this and it is desirable to provide an injection device wherein the forward driving force is applied to the syringe, not to the liquid drug therein.

6. As already identified by the examiner, there is a critical difference between the D1 and D2 devices. The D1 device applies driving force to the flange of the syringe barrel in order to move the needle forward, ready for injection. In contrast, the D2 device applies driving force to the liquid drug itself inside the syringe, using its incompressible nature to cause the needle to move forward, ready for injection. These two different types of technology are incompatible with one another.

Regarding inventive step, the closest prior art appears to be D1. Taking this as a starting point, the technical problem to be solved is how to provide an injection device wherein the needle automatically retracts into the housing after injection.

Starting with the teaching of the D1, and assuming the skilled person wanted to modify the D1 device so that its needle could retract after the injection, there is no reason why the skilled reader would look to the teaching of D2 to supply the missing feature, given the significant technical differences between the D1 and D2 devices.

Even if the skilled person tried to combine the teachings of D1 and D2 in order to make the D1 device have a retractable needle, D2 would lead him to modify the pressure plate 26 and end 112 of the ejection member of D1 into an arrangement equivalent to the rod end 27A and aperture in the drive member 8 of D2, so that the "retractable" D1 device would be of the type which applies driving force to the liquid drug inside the syringe i.e. leading further away from the invention claimed in the present application.

In other words, either the device acts on the barrel to move the needle forward (as in D1), in which case the needle cannot retract, or the device acts on the liquid drug to move the needle forward (as in D2), in which case the needle can retract but the inner housing is never "intermediate the outer housing and the barrel and plunger" as required by claim 1.

It is therefore clear that the claimed invention is not obvious in light of D1 and D2.

7. The description has been brought into conformity with the amended claims on replacement pages 2-8 filed herewith.

The deletion of any subject matter from the present application should not be construed as abandonment of that subject matter and is not without prejudice to its reinstatement or to filing a divisional application for that subject matter.

The examiner is invited to contact the undersigned if any point remains outstanding that can be usefully resolved by telephone.

Oral proceedings are requested if the examiner contemplates refusing the application.

I enclose two copies of EPO Form 1037, and I should be grateful if you would stamp and return one of these to us immediately as an acknowledgement of receipt of this letter and enclosures.

Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote

INJECTION DEVICE

This invention relates to the field of injection devices for the administration of liquid medication, for example, insulin or growth hormone.

One type of injection device is known as a mini-needle or micro-needle device. These devices comprise a pressurised ("forced") injection system and have a needle which is shorter than that of conventional needle systems. The needle is normally hidden which is advantageous both for avoiding needle stick injuries and for minimising trauma to needle-phobic patients. The needle is hidden both before and after the injection is delivered, appearing only for the duration of the injection. Mini needle devices can typically deliver a larger volume of medication than needle-free devices and can deliver faster than conventional needle systems.

One such known device is described in WO00/09186 (Medi-Ject Corporation) for "Needle assisted jet injector" and this document gives a useful summary of prior art devices.

The device of WO 00/09186 includes a needle which is, in one embodiment, retractably located within an injector nozzle assembly. Upon activation of a force generating source, a portion of the needle extends past the nozzle assembly and penetrates the outer layer of skin to deliver medicament via jet injection to a deeper region. After activation, the needle retracts back into the nozzle assembly. The retractable needle is housed within the nozzle and is pushed forward so that it emerges in order to deliver an injection by the liquid medicament itself, when the medicament is itself pushed forward by the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

WO03/097133 (Owen Mumford) discloses an injection device with a retractable needle but with driving force applied to the liquid inside the syringe, using the liquid's incompressible nature to cause the needle to move forward. A relatively complex arrangement is required for this and it would be desirable to provide an injection device wherein the forward driving force is applied to the syringe, not to the liquid drug therein.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing adapted to receive

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing is in communication with both the plunger and the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which the inner housing is in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

The injection device according to the present invention provides a simple and cost-effective means of delivering medicament through a retractable needle. If desired, the device is able to deliver medicament to a depth beyond the length of the needle because of the propulsive force provided by the energy source. As mentioned above, the injection device is equally suitable for needle-assisted jet injection (delivering medicament to a depth beyond the length of the needle), conventional injection (to the depth of the needle penetration), or even to a user-adjustable needle penetration depth.

The device requires that the needle (and hence also the barrel to which it is normally fixed) is moved axially so

that the needle can appear beyond the end of the nozzle for the duration of the injection, after which the needle retracts automatically, out of sight of the user. The device also requires that the plunger is moved axially (into the barrel) so that medicament is ejected. The overall complexity of the injection device is significantly reduced by both of these requirements being effected by one component, namely the inner housing.

Preferably, the injection device comprises an outer housing inside which is located said barrel, said needle and said plunger.

Preferably, said inner housing includes one or more radially flexible tags, each preferably located at the end of a resiliently flexible leg.

Preferably, one or more of said tags are situated at the rear end of the inner housing and are moveable radially into and out of communication with the plunger. In one embodiment, the tags are biased radially inwardly into communication with the plunger, preferably by communication with the outer housing. Alternatively, the tags are stored in their relaxed condition, before an injection is initiated.

Each rear tag may be moveable out of communication with the plunger when aligned with a corresponding recess in the outer housing. Preferably, each rear tag is substantially T-shaped. One leg of the T-shape enables the rear tag to hook over the plunger and, effectively, pull the plunger forward (in the first and second positions mentioned above). The other leg of the T-shape enables the rear tag to move radially outwardly to catch in a recess in the housing (in the third position mentioned above).

Preferably, one or more of said tags are situated at the forward end of the inner housing and are moveable radially into and out of communication with the barrel. In one embodiment, the forward tags are biased radially inwardly into communication with the barrel, preferably by communication with the outer housing. Alternatively, the forward tags are stored in their relaxed condition, before initiating an injection.

Each forward tag may be moveable out of communication with the barrel when aligned with a corresponding recess in the outer housing. Preferably, each rear tag is substantially L-shaped.

In a preferred embodiment, said energy source is a compressed gas. Alternatively, said energy source is a spring.

Preferably, the injection device further includes means for allowing the inner housing to move axially only forward with respect to the outer housing. Ideally, said means is an arrangement of serrations, barbs, ratchet teeth or the like intermediate the housings.

Preferably, the injection device further comprises guide means for guiding, in use, the relative axial movement of the inner and outer housings, the guide means preferably comprising one or more protrusions on said inner housing which, in use, cooperate with corresponding recesses on an interior surface of said outer housing.

Preferably, said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer housing.

In one embodiment, the needle is removable from the device, this being of benefit in applications where the device is reusable (for example if a multiple-use cartridge of medicament is utilised).

In a further embodiment, said needle, barrel and plunger are removable from said device. It is intended that the device of the present invention could be constructed around a standard needle, barrel and plunger of known type.

Preferably, the injection device further includes a removable needle cover which protects the needle during storage and before use. Advantageously, said needle cover includes means for pulling a protective rubber sheath or the like from said needle when said needle cover is removed from the device. Said pulling means may include a floating rivet intermediate the needle cover and the protective rubber sheath or the like, whereby twisting forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

Preferably, the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

In a preferred form, the injection device further comprises a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place. Preferably, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

Preferably, the injection device includes means for emitting an audible and/or physical indication to a user that the injection is complete.

Preferred embodiments of the present invention will now be more particularly described, by way of example only, with reference to the accompanying drawings wherein:

Figure 1 is a perspective view, partly in section, showing the injection device, in the condition in which it is supplied to a user, apart from the needle cover;

Figure 2, drawn to a larger scale, shows detail of part of the device shown in Figure 1;

Figure 3 is a perspective view, partly in section, showing the injection device, during an injection;

Figure 4, drawn to a larger scale, shows detail of part of the device shown in Figure 3;

Figure 5 is a perspective view, partly in section, showing the injection device, with the plunger fully depressed into the barrel;

Figure 6, drawn to a larger scale, shows detail of part of the device shown in Figure 5;

Figure 7 is a perspective view, partly in section,

CLAIMS

1. An injection device comprising an outer housing (30) adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7), characterised in that the inner housing (7) is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

2. The injection device of claim 1 inside which is located

said barrel for holding a volume of a medicament;

said needle (10) at one end of the barrel; and

said plunger (8), axially moveable within the barrel.

3. An injection device as claimed in claim 1 or claim 2 further comprising a spring housing (41) intermediate the outer housing (30) and the inner housing (7).

4. An injection device as claimed in any of the preceding claims wherein one or more of said tags is located at the end of a resiliently flexible leg.

5. An injection device as claimed in any of the preceding claims wherein one or more of said tags are situated at the rear end of the inner housing and are moveable radially into and out of communication with the plunger.

6. An injection device as claimed in any of claims 3-5 wherein said tags are biased radially inwardly into communication with said plunger, preferably by communication with said spring housing.

7. An injection device as claimed in any of the preceding claims wherein said tags are stored in their relaxed condition, before initiating an injection.

8. An injection device as claimed in any of claims 3-7 wherein each rear tag is moveable out of communication with the plunger when aligned with a

corresponding recess in the spring housing.

9. An injection device as claimed in any of the preceding claims wherein each rear tag is substantially T-shaped.

10. An injection device as claimed in any of claims 1-4 wherein one or more of said tags are situated at the forward end of the inner housing and are moveable radially into and out of communication with the barrel.

11. An injection device as claimed in claim 10 wherein said forward tags are biased radially inwardly into communication with said barrel, preferably by communication with said spring housing.

12. An injection device as claimed in claim 10 or claim 11 wherein said forward tags are stored in their relaxed condition, before initiating an injection.

13. An injection device as claimed in any of claims 10-12 wherein each forward tag is moveable out of communication with the barrel when aligned with a corresponding recess in the spring housing.

14. An injection device as claimed in any of claims 10-13 wherein each forward tag is substantially L-shaped.

15. An injection device as claimed in any of the preceding claims wherein said energy source is a compressed gas.

16. An injection device as claimed in any of claims 1-14 wherein said energy source is a spring.

17. An injection device as claimed in any of the preceding claims further including means for allowing the inner housing to move axially only forward with respect to the outer housing.

18. An injection device as claimed in claim 17 wherein said means is an arrangement of serrations, barbs, ratchet teeth or the like intermediate the housings.

19. An injection device as claimed in any of the preceding claims further comprising guide means for guiding, in use, the relative axial movement of the spring and outer housings, the guide means preferably comprising one or more protrusions on said spring housing which, in use, cooperate with corresponding recesses on an interior surface of said outer housing.

20. An injection device as claimed in any of the preceding claims wherein said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer and/or spring housing.

21. An injection device as claimed in any of the preceding claims wherein the needle is removable from said device.

22. An injection device as claimed in any of the preceding claims wherein said needle, barrel and plunger are removable from said device.

23. An injection device as claimed in any of the preceding claims further including a removable needle cover which protects the needle during storage before use.

24. An injection device as claimed in claim 23 wherein said needle cover includes means for pulling a protective rubber sheath or the like from said needle when said needle cover is removed from the device.

25. An injection device as claimed in claim 24 wherein said pulling means includes a floating rivet intermediate the needle cover and the protective rubber sheath or the like, whereby twisting forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

26. An injection device as claimed in any of claims 23-25 wherein the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

27. An injection device as claimed in any of the preceding claims further comprising a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place.

28. An injection device as claimed in claim 27 wherein, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

29. An injection device as claimed in any of the preceding claims further comprising means for emitting an audible and/or physical indication to a user that the injection is complete.

the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

WO03/097133 (Owen Mumford) discloses an injection device with a retractable needle but with driving force applied to the liquid inside the syringe, using the liquid's incompressible nature to cause the needle to move forward. A relatively complex arrangement is required for this and it would be desirable to provide an injection device wherein the forward driving force is applied to the syringe, not to the liquid drug therein.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing ~~inside which is located~~adapted to receive

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is

such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

The injection device according to the present invention provides a simple and cost-effective means of delivering medicament through a retractable needle. If desired, the device is able to deliver medicament to a depth beyond the length of the needle because of the propulsive force provided by the energy source. As mentioned above, the injection device is equally suitable for needle-assisted jet injection (delivering medicament to a depth beyond the length of the needle), conventional injection (to the depth of the needle penetration), or even to a user-adjustable needle penetration depth.

The device requires that the needle (and hence also the barrel to which it is normally fixed) is moved axially so that the needle can appear beyond the end of the nozzle for the duration of the injection, after which the needle retracts automatically, out of sight of the user. The device also requires that the plunger is moved axially (into the barrel) so that medicament is ejected. The overall complexity of the injection device is significantly reduced by both of these requirements being effected by one component, namely the inner housing.

Preferably, the injection device comprises an outer housing inside which is located said barrel, said needle and said plunger.

Preferably, said inner housing includes one or more radially flexible tags, each preferably located at the end of a resiliently flexible leg.

forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

Preferably, the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

In a preferred form, the injection device further comprises a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place. Preferably, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

Preferably, the injection device includes means for emitting an audible and/or physical indication to a user that the injection is complete.

~~According to a second aspect of the invention there is provided an injection device comprising an outer housing inside which is located~~

~~a barrel for holding a volume of a medicament;~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;~~

~~a plunger, axially moveable within the barrel;~~

~~an inner housing intermediate the outer housing and the barrel and plunger; and~~

~~an energy source in communication with said inner housing;~~

~~wherein the inner housing is moveable by the energy source between two positions, namely~~

~~a first position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a second position in which the inner housing is in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

~~According to a third aspect of the invention there is provided an injection device comprising an outer housing adapted to receive:~~

~~a barrel for holding a volume of a medicament;~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing; and~~

~~a plunger, axially moveable within the barrel,~~

~~characterised in that the injection device further comprises:~~

~~an inner housing intermediate the outer housing and the barrel and plunger; and~~

~~an energy source in communication with said inner housing,~~

~~wherein the inner housing is moveable by the energy source between three positions, namely~~

~~a first position in which the inner housing is in communication with both the plunger and the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;~~

~~a second position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a third position in which the inner housing is in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

Preferred embodiments of the present invention will now be more particularly described, by way of example only, with reference to the accompanying drawings wherein:

Figure 1 is a perspective view, partly in section, showing the injection device, in the condition in which it is supplied to a user, apart from the needle cover;

Figure 2, drawn to a larger scale, shows detail of part of the device shown in Figure 1;

Figure 3 is a perspective view, partly in section, showing the injection device, during an injection;

Figure 4, drawn to a larger scale, shows detail of part of the device shown in Figure 3;

Figure 5 is a perspective view, partly in section, showing the injection device, with the plunger fully depressed into the barrel;

Figure 6, drawn to a larger scale, shows detail of part of the device shown in Figure 5;

Figure 7 is a perspective view, partly in section,

CLAIMS

1. ~~30.~~ An injection device comprising an outer housing (30) adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7),

characterised in that the inner housing (7) is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

~~1.~~2. ~~An~~ The injection device ~~comprising an outer housing (30)~~of claim 1 inside which is located

~~a~~ said barrel for holding a volume of a ~~medicament;~~

~~a~~ said needle (10) at one end of the barrel~~,~~; ~~the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing;~~and

~~a~~ said plunger (8), axially moveable within the ~~barrel~~.

~~an inner housing (7) intermediate the outer housing and the barrel and plunger; and~~

~~an energy source (1; 40) in communication with said inner housing (7),~~

~~characterised in that the inner housing (7) is moveable by the energy source between three positions, namely~~

~~a first position in which the inner housing has one or more radially flexible tags (7B) which are in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;~~

~~a second position in which the inner housing has one or more radially flexible tags (7A) which are in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a third position in which said one or more radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

~~2.~~3. An injection device as claimed in claim 1 or claim 2 further comprising a spring housing (41) intermediate the outer housing (30) and the inner housing (7).

~~3.~~4. An injection device as claimed in any of the preceding claims ~~1~~ wherein one or more of said tags is located at the end of a resiliently flexible leg.

~~4.~~5. An injection device as claimed in any of the preceding claims wherein one or more of said tags are situated at the rear end of the inner housing and are moveable radially into and out of communication with the plunger.

~~5.~~6. An injection device as claimed in any of claims ~~2-4~~3-5 wherein said tags are biased radially inwardly into communication with said plunger, preferably by communication with said spring housing.

~~6.~~7. An injection device as claimed in any of the preceding claims wherein said tags are stored in their relaxed condition, before initiating an injection.

~~7.~~8. An injection device as claimed in any of claims ~~2-6~~3-7 wherein each rear tag is moveable out of communication with the plunger when aligned with a corresponding recess in the spring housing.

~~8.~~9. An injection device as claimed in any of the preceding claims wherein each rear tag is substantially T-shaped.

~~9.~~10. An injection device as claimed in any of claims 1-~~4~~3

_wherein one or more of said tags are situated at the forward end of the inner housing and are moveable radially into and out of communication with the barrel.

~~10.~~11. ~~—~~An injection device as claimed in claim ~~9—~~10 wherein said forward tags are biased radially inwardly into communication with said barrel, preferably by communication with said spring housing.

~~11.~~12. ~~—~~An injection device as claimed in claim ~~9—~~10 or claim 11~~0~~ wherein said forward tags are stored in their relaxed condition, before initiating an injection.

~~12.~~13. ~~—~~An injection device as claimed in any of claims ~~9-11~~10-12 wherein each forward tag is moveable out of communication with the barrel when aligned with a corresponding recess in the spring housing.

~~13.~~14. ~~—~~An injection device as claimed in any of claims ~~9-12~~10-13 wherein each forward tag is substantially L-shaped.

~~14.~~15. An injection device as claimed in any of the preceding claims wherein said energy source is a compressed gas.

~~15.~~16. An injection device as claimed in any of claims 1-~~13—~~14 wherein said energy source is a spring.

~~16.~~17. ~~—~~An injection device as claimed in any of the preceding claims further including means for allowing the inner housing to move axially only forward with respect to the outer housing

~~.~~

~~17~~18. ~~.~~ An injection device as claimed in claim ~~16~~17 wherein said means is an arrangement of serrations, barbs, ratchet teeth or the like intermediate the housings.

~~18.~~19. ~~—~~An injection device as claimed in any of the preceding claims further comprising guide means for guiding, in use, the relative axial movement of the spring and outer housings, the guide means preferably comprising one or more protrusions on said spring housing which, in use, cooperate with corresponding recesses on an interior surface of said outer housing.

~~19.~~20. ~~—~~An injection device as claimed in any of the preceding claims wherein said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer and/or spring housing.

~~20.~~21. ~~—~~An injection device as claimed in any of the preceding claims wherein the needle is removable from said device.

~~21.~~22. ~~—~~An injection device as claimed in any of the preceding claims wherein said needle, barrel and plunger are removable from said device.

~~22.~~23. ~~—~~An injection device as claimed in any of the preceding claims further including a removable needle cover which protects the needle during storage before use.

~~23.~~24. ~~—~~An injection device as claimed in claim ~~22~~23 wherein said needle cover includes means for pulling a

protective rubber sheath or the like from said needle when said needle cover is removed from the device.

~~24.~~25. ~~—~~An injection device as claimed in claim ~~23—~~24 wherein said pulling means includes a floating rivet intermediate the needle cover and the protective rubber sheath or the like, whereby twisting forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

~~25.~~26. ~~—~~An injection device as claimed in any of claims ~~22~~23-~~24—~~25 wherein the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

~~26.~~27. An injection device as claimed in any of the preceding claims further comprising a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place.

~~27.~~28. ~~—~~An injection device as claimed in claim ~~26—~~27 wherein, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

~~28.~~29. ~~—~~An injection device as claimed in any of the preceding claims further comprising means for emitting an audible and/or physical indication to a user that the injection is complete.

~~29. An injection device comprising an outer housing inside which is located~~

~~a barrel for holding a volume of a medicament;~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;~~

~~a plunger, axially moveable within the barrel;~~

~~an inner housing intermediate the outer housing and the barrel and plunger; and~~

~~an energy source in communication with said inner housing,~~

~~characterised in that the inner housing is moveable by the energy source between two positions, namely~~

~~a first position in which the inner housing has one or more radially flexible tags which are in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a second position in which said one or more radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

~~30. An injection device comprising an outer housing adapted to receive:~~

~~a barrel for holding a volume of a medicament;~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing; and~~

~~a plunger, axially moveable within the barrel,~~

~~wherein the injection device further comprises:~~

~~an inner housing intermediate the outer housing and the barrel and plunger; and~~

~~an energy source in communication with said inner housing,~~

~~characterised in that the inner housing is moveable by the energy source between three positions, namely~~

~~a first position in which the inner housing has one or more radially flexible tags in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;~~

~~a second position in which the inner housing has one or more radially flexible tags in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a third position in which said radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

~~31.~~ An injection device as ~~claimed~~ in ~~claim 29 or claim 30 having all of the features of any of claims 2 28.~~

HGF
Harrison Goddard Foote
Patent and Trade Mark
Attorneys

European Patent Office
Erhardtstrasse 27
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10 November 2006

Your ref: REINBOLD, Sylvie
Our ref: VJS/P103497EP

By Fax: 0049 89 2399 4465
Sender: Vanessa Stainthorpe
Pages: 30 inc this page

Dear Sirs

European Patent Application No 05701985.3
Auto Safety Injector
The Medical House plc

We are writing in response to your communication pursuant to Article 96(2) EPC dated 30 October 2006. A PACE Request was filed 27.09.2006 and we respectfully request that this response is handled as quickly as possible.

With this letter we are filing the following replacement pages, amended in light of the examiner's comments:

Description: pages 2-7 (previous page 8 should be removed and the remaining pages renumbered accordingly)
Claims: Claims 1-29

A further copy of the relevant pages is enclosed on which the amendments have been indicated for the examiner's reference.

Clarity – Article 84 EPC

The examiner objected to the three independent claims 1, 29 and 30. Whilst the applicant does not believe there to be a lack of clarity, in the interest of expedient prosecution, claim 29 has been deleted. Claim 30 has been recast as the main claim, with former claim 1 dependent thereon, so that there now is only one independent claim in this application. Basis for making claim 30 be the main claim with the other claims dependent thereon is found in former claim 31, which has also now been deleted.

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Other Matters

The paragraph numbering below corresponds with the paragraph numbering in the examiner's communication.

3. Reference signs in parentheses have been added to new claim 1 (former claim 30).

4. Former claim 1 was indeed already in two-part form, but this issue is no longer relevant given the amendment to this claim, which is now dependent claim 2. New claim 1 (former claim 30) is also already in two-part form.

5. Document D1 was already identified and discussed on page 2 of the description filed upon entry into the European regional phase. Document D2 is identified and discussed on replacement page 2 filed herewith. D2, namely WO03/097133 (Owen Mumford) discloses an injection device with a retractable needle but with the driving force applied to the liquid inside the syringe, using the liquid's incompressible nature to cause the needle to move forward. A relatively complex arrangement is required for this and it is desirable to provide an injection device wherein the forward driving force is applied to the syringe, not to the liquid drug therein.

6. As already identified by the examiner, there is a critical difference between the D1 and D2 devices. The D1 device applies driving force to the flange of the syringe barrel in order to move the needle forward, ready for injection. In contrast, the D2 device applies driving force to the liquid drug itself inside the syringe, using its incompressible nature to cause the needle to move forward, ready for injection. These two different types of technology are incompatible with one another.

Regarding inventive step, the closest prior art appears to be D1. Taking this as a starting point, the technical problem to be solved is how to provide an injection device wherein the needle automatically retracts into the housing after injection.

Starting with the teaching of the D1, and assuming the skilled person wanted to modify the D1 device so that its needle could retract after the injection, there is no reason why the skilled reader would look to the teaching of D2 to supply the missing feature, given the significant technical differences between the D1 and D2 devices.

Even if the skilled person tried to combine the teachings of D1 and D2 in order to make the D1 device have a retractable needle, D2 would lead him to modify the pressure plate 26 and end 112 of the ejection member of D1 into an arrangement equivalent to the rod end 27A and aperture in the drive member 8 of D2, so that the "retractable" D1 device would be of the type which applies driving force to the liquid drug inside the syringe i.e. leading further away from the invention claimed in the present application.

In other words, either the device acts on the barrel to move the needle forward (as in D1), in which case the needle cannot retract, or the device acts on the liquid drug to move the needle forward (as in D2), in which case the needle can retract but the inner housing is never "intermediate the outer housing and the barrel and plunger" as required by claim 1.

It is therefore clear that the claimed invention is not obvious in light of D1 and D2.

7. The description has been brought into conformity with the amended claims on replacement pages 2-8 filed herewith.

The deletion of any subject matter from the present application should not be construed as abandonment of that subject matter and is not without prejudice to its reinstatement or to filing a divisional application for that subject matter.

The examiner is invited to contact the undersigned if any point remains outstanding that can be usefully resolved by telephone.

Oral proceedings are requested if the examiner contemplates refusing the application.

I enclose two copies of EPO Form 1037, and I should be grateful if you would stamp and return one of these to us immediately as an acknowledgement of receipt of this letter and enclosures.

Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote

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1.	05701985.3	P103497EP	Faxed letter of 10.11.06
2.		Medical House	Replacement pgs 1-7
3.			Replacement Claims 1-29
4.			
5.			
6.			
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9.			
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	Anmeldenummer/Patentnummer Application Number/Patent Number Numéro de la demande/numéro du brevet	Ihr Zeichen Your reference Votre référence	ggfs. Art und Datum der Unterlagen [3] Nature and date of items (optional) [3] Nature et date des pièces (facultatif) [3]
1.	05701985.3	P103497EP	Faxed letter of 10.11.06
2.		Medical House	Replacement pgs 1-7
3.			Replacement Claims 1-29
4.			
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the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

WO03/097133 (Owen Mumford) discloses an injection device with a retractable needle but with driving force applied to the liquid inside the syringe, using the liquid's incompressible nature to cause the needle to move forward. A relatively complex arrangement is required for this and it would be desirable to provide an injection device wherein the forward driving force is applied to the syringe, not to the liquid drug therein.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing ~~inside which is located~~adapted to receive

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is

such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

The injection device according to the present invention provides a simple and cost-effective means of delivering medicament through a retractable needle. If desired, the device is able to deliver medicament to a depth beyond the length of the needle because of the propulsive force provided by the energy source. As mentioned above, the injection device is equally suitable for needle-assisted jet injection (delivering medicament to a depth beyond the length of the needle), conventional injection (to the depth of the needle penetration), or even to a user-adjustable needle penetration depth.

The device requires that the needle (and hence also the barrel to which it is normally fixed) is moved axially so that the needle can appear beyond the end of the nozzle for the duration of the injection, after which the needle retracts automatically, out of sight of the user. The device also requires that the plunger is moved axially (into the barrel) so that medicament is ejected. The overall complexity of the injection device is significantly reduced by both of these requirements being effected by one component, namely the inner housing.

Preferably, the injection device comprises an outer housing inside which is located said barrel, said needle and said plunger.

Preferably, said inner housing includes one or more radially flexible tags, each preferably located at the end of a resiliently flexible leg.

_forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

Preferably, the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

In a preferred form, the injection device further comprises a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place. Preferably, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

Preferably, the injection device includes means for emitting an audible and/or physical indication to a user that the injection is complete.

~~According to a second aspect of the invention there is provided an injection device comprising an outer housing inside which is located~~

~~a barrel for holding a volume of a medicament,~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing,~~

~~a plunger, axially moveable within the barrel,~~

~~an inner housing intermediate the outer housing and the barrel and plunger, and~~

~~an energy source in communication with said inner housing,~~

~~wherein the inner housing is moveable by the energy source between two positions, namely~~

~~a first position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a second position in which the inner housing is in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

~~According to a third aspect of the invention there is provided an injection device comprising an outer housing adapted to receive:~~

~~a barrel for holding a volume of a medicament,~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing; and~~

~~a plunger, axially moveable within the barrel,~~

~~characterised in that the injection device further comprises:~~

~~an inner housing intermediate the outer housing and the barrel and plunger; and~~

~~an energy source in communication with said inner housing,~~

~~wherein the inner housing is moveable by the energy source between three positions, namely~~

~~a first position in which the inner housing is in communication with both the plunger and the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;~~

~~a second position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a third position in which the inner housing is in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

Preferred embodiments of the present invention will now be more particularly described, by way of example only, with reference to the accompanying drawings wherein:

Figure 1 is a perspective view, partly in section, showing the injection device, in the condition in which it is supplied to a user, apart from the needle cover;

Figure 2, drawn to a larger scale, shows detail of part of the device shown in Figure 1;

Figure 3 is a perspective view, partly in section, showing the injection device, during an injection;

Figure 4, drawn to a larger scale, shows detail of part of the device shown in Figure 3;

Figure 5 is a perspective view, partly in section, showing the injection device, with the plunger fully depressed into the barrel;

Figure 6, drawn to a larger scale, shows detail of part of the device shown in Figure 5;

Figure 7 is a perspective view, partly in section,

CLAIMS

1. ~~30.~~ An injection device comprising an outer housing (30) ~~—~~ adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7),

characterised in that the inner housing (7) is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

~~1.~~2. ~~An~~ The injection device ~~comprising an outer housing (30)~~ of claim 1 inside which is located

~~a~~ said barrel for holding a volume of a ~~medicament;~~

~~a~~ said needle (10) at one end of the barrel~~,~~; ~~the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing;~~ and

~~a~~ said plunger (8), axially moveable within the ~~barrel~~.

~~an inner housing (7) intermediate the outer housing and the barrel and plunger; and~~

~~an energy source (1, 40) in communication with said inner housing (7),~~

~~characterised in that the inner housing (7) is moveable by the energy source between three positions, namely~~

~~a first position in which the inner housing has one or more radially flexible tags (7B) which are in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;~~

~~a second position in which the inner housing has one or more radially flexible tags (7A) which are in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a third position in which said one or more radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

~~2.~~3. An injection device as claimed in claim 1 or claim 2 further comprising a spring housing (41) intermediate the outer housing (30) and the inner housing (7).

~~3.~~4. An injection device as claimed in any of the preceding claims ~~1~~ wherein one or more of said tags is located at the end of a resiliently flexible leg.

~~4.~~5. An injection device as claimed in any of the preceding claims wherein one or more of said tags are situated at the rear end of the inner housing and are moveable radially into and out of communication with the plunger.

~~5.~~6. An injection device as claimed in any of claims ~~2-4~~3-5 wherein said tags are biased radially inwardly into communication with said plunger, preferably by communication with said spring housing.

~~6.~~7. An injection device as claimed in any of the preceding claims wherein said tags are stored in their relaxed condition, before initiating an injection.

~~7.~~8. An injection device as claimed in any of claims ~~2-6~~3-7 wherein each rear tag is moveable out of communication with the plunger when aligned with a corresponding recess in the spring housing.

~~8.~~9. An injection device as claimed in any of the preceding claims wherein each rear tag is substantially T-shaped.

~~9.~~10. An injection device as claimed in any of claims 1-~~4~~3

_wherein one or more of said tags are situated at the forward end of the inner housing and are moveable radially into and out of communication with the barrel.

~~10.~~11. ~~—~~An injection device as claimed in claim ~~9~~ 10 wherein said forward tags are biased radially inwardly into communication with said barrel, preferably by communication with said spring housing.

~~11.~~12. ~~—~~An injection device as claimed in claim ~~9~~ 10 or claim 1~~0~~ wherein said forward tags are stored in their relaxed condition, before initiating an injection.

~~12.~~13. ~~—~~An injection device as claimed in any of claims ~~9 11~~10-12 wherein each forward tag is moveable out of communication with the barrel when aligned with a corresponding recess in the spring housing.

~~13.~~14. ~~—~~An injection device as claimed in any of claims ~~9 12~~10-13 wherein each forward tag is substantially L-shaped.

~~14.~~15. An injection device as claimed in any of the preceding claims wherein said energy source is a compressed gas.

~~15.~~16. An injection device as claimed in any of claims 1-~~13~~ 14 wherein said energy source is a spring.

~~16.~~17. ~~—~~An injection device as claimed in any of the preceding claims further including means for allowing the inner housing to move axially only forward with respect to the outer housing

~~17~~18. ~~-~~ An injection device as claimed in claim ~~16~~17 wherein said means is an arrangement of serrations, barbs, ratchet teeth or the like intermediate the housings.

~~18.~~19. ~~—~~An injection device as claimed in any of the preceding claims further comprising guide means for guiding, in use, the relative axial movement of the spring and outer housings, the guide means preferably comprising one or more protrusions on said spring housing which, in use, cooperate with corresponding recesses on an interior surface of said outer housing.

~~19.~~20. ~~—~~An injection device as claimed in any of the preceding claims wherein said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer and/or spring housing.

~~20.~~21. ~~—~~An injection device as claimed in any of the preceding claims wherein the needle is removable from said device.

~~21.~~22. ~~—~~An injection device as claimed in any of the preceding claims wherein said needle, barrel and plunger are removable from said device.

~~22.~~23. ~~—~~An injection device as claimed in any of the preceding claims further including a removable needle cover which protects the needle during storage before use.

~~23.~~24. ~~—~~An injection device as claimed in claim 2~~2~~3 wherein said needle cover includes means for pulling a

protective rubber sheath or the like from said needle when said needle cover is removed from the device.

~~24.~~25. ~~—~~An injection device as claimed in claim ~~23—~~24 wherein said pulling means includes a floating rivet intermediate the needle cover and the protective rubber sheath or the like, whereby twisting forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

~~25.~~26. ~~—~~An injection device as claimed in any of claims ~~2223-24—~~25 wherein the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

~~26.~~27. An injection device as claimed in any of the preceding claims further comprising a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place.

~~27.~~28. ~~—~~An injection device as claimed in claim ~~26—~~27 wherein, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

~~28.~~29. ~~—~~An injection device as claimed in any of the preceding claims further comprising means for emitting an audible and/or physical indication to a user that the injection is complete.

~~29. An injection device comprising an outer housing inside which is located~~

~~a barrel for holding a volume of a medicament,~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing,~~

~~a plunger, axially moveable within the barrel,~~

~~an inner housing intermediate the outer housing and the barrel and plunger, and~~

~~an energy source in communication with said inner housing,~~

~~characterised in that the inner housing is moveable by the energy source between two positions, namely~~

~~a first position in which the inner housing has one or more radially flexible tags which are in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and~~

~~a second position in which said one or more radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.~~

~~30. An injection device comprising an outer housing adapted to receive:~~

~~a barrel for holding a volume of a medicament,~~

~~a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing; and~~

a plunger, axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

characterised in that the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing,

a second position in which the inner housing has one or more radially flexible tags in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

31. An injection device as claimed in claim 29 or claim 30 having all of the features of any of claims 2-28.

INJECTION DEVICE

This invention relates to the field of injection devices for the administration of liquid medication, for example, insulin or growth hormone.

One type of injection device is known as a mini-needle or micro-needle device. These devices comprise a pressurised ("forced") injection system and have a needle which is shorter than that of conventional needle systems. The needle is normally hidden which is advantageous both for avoiding needle stick injuries and for minimising trauma to needle-phobic patients. The needle is hidden both before and after the injection is delivered, appearing only for the duration of the injection. Mini needle devices can typically deliver a larger volume of medication than needle-free devices and can deliver faster than conventional needle systems.

One such known device is described in WO00/09186 (Medi-Ject Corporation) for "Needle assisted jet injector" and this document gives a useful summary of prior art devices.

The device of WO 00/09186 includes a needle which is, in one embodiment, retractably located within an injector nozzle assembly. Upon activation of a force generating source, a portion of the needle extends past the nozzle assembly and penetrates the outer layer of skin to deliver medicament via jet injection to a deeper region. After activation, the needle retracts back into the nozzle assembly. The retractable needle is housed within the nozzle and is pushed forward so that it emerges in order to deliver an injection by the liquid medicament itself, when the medicament is itself pushed forward by the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

WO03/097133 (Owen Mumford) discloses an injection device with a retractable needle but with driving force applied to the liquid inside the syringe, using the liquid's incompressible nature to cause the needle to move forward. A relatively complex arrangement is required for this and it would be desirable to provide an injection device wherein the forward driving force is applied to the syringe, not to the liquid drug therein.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing adapted to receive

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing is in communication with both the plunger and the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which the inner housing is in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

The injection device according to the present invention provides a simple and cost-effective means of delivering medicament through a retractable needle. If desired, the device is able to deliver medicament to a depth beyond the length of the needle because of the propulsive force provided by the energy source. As mentioned above, the injection device is equally suitable for needle-assisted jet injection (delivering medicament to a depth beyond the length of the needle), conventional injection (to the depth of the needle penetration), or even to a user-adjustable needle penetration depth.

The device requires that the needle (and hence also the barrel to which it is normally fixed) is moved axially so

that the needle can appear beyond the end of the nozzle for the duration of the injection, after which the needle retracts automatically, out of sight of the user. The device also requires that the plunger is moved axially (into the barrel) so that medicament is ejected. The overall complexity of the injection device is significantly reduced by both of these requirements being effected by one component, namely the inner housing.

Preferably, the injection device comprises an outer housing inside which is located said barrel, said needle and said plunger.

Preferably, said inner housing includes one or more radially flexible tags, each preferably located at the end of a resiliently flexible leg.

Preferably, one or more of said tags are situated at the rear end of the inner housing and are moveable radially into and out of communication with the plunger. In one embodiment, the tags are biased radially inwardly into communication with the plunger, preferably by communication with the outer housing. Alternatively, the tags are stored in their relaxed condition, before an injection is initiated.

Each rear tag may be moveable out of communication with the plunger when aligned with a corresponding recess in the outer housing. Preferably, each rear tag is substantially T-shaped. One leg of the T-shape enables the rear tag to hook over the plunger and, effectively, pull the plunger forward (in the first and second positions mentioned above). The other leg of the T-shape enables the rear tag to move radially outwardly to catch in a recess in the housing (in the third position mentioned above).

Preferably, one or more of said tags are situated at the forward end of the inner housing and are moveable radially into and out of communication with the barrel. In one embodiment, the forward tags are biased radially inwardly into communication with the barrel, preferably by communication with the outer housing. Alternatively, the forward tags are stored in their relaxed condition, before initiating an injection.

Each forward tag may be moveable out of communication with the barrel when aligned with a corresponding recess in the outer housing. Preferably, each rear tag is substantially L-shaped.

In a preferred embodiment, said energy source is a compressed gas. Alternatively, said energy source is a spring.

Preferably, the injection device further includes means for allowing the inner housing to move axially only forward with respect to the outer housing. Ideally, said means is an arrangement of serrations, barbs, ratchet teeth or the like intermediate the housings.

Preferably, the injection device further comprises guide means for guiding, in use, the relative axial movement of the inner and outer housings, the guide means preferably comprising one or more protrusions on said inner housing which, in use, cooperate with corresponding recesses on an interior surface of said outer housing.

Preferably, said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer housing.

In one embodiment, the needle is removable from the device, this being of benefit in applications where the device is reusable (for example if a multiple-use cartridge of medicament is utilised).

In a further embodiment, said needle, barrel and plunger are removable from said device. It is intended that the device of the present invention could be constructed around a standard needle, barrel and plunger of known type.

Preferably, the injection device further includes a removable needle cover which protects the needle during storage and before use. Advantageously, said needle cover includes means for pulling a protective rubber sheath or the like from said needle when said needle cover is removed from the device. Said pulling means may include a floating rivet intermediate the needle cover and the protective rubber sheath or the like, whereby twisting forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

Preferably, the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

In a preferred form, the injection device further comprises a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place. Preferably, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

Preferably, the injection device includes means for emitting an audible and/or physical indication to a user that the injection is complete.

Preferred embodiments of the present invention will now be more particularly described, by way of example only, with reference to the accompanying drawings wherein:

Figure 1 is a perspective view, partly in section, showing the injection device, in the condition in which it is supplied to a user, apart from the needle cover;

Figure 2, drawn to a larger scale, shows detail of part of the device shown in Figure 1;

Figure 3 is a perspective view, partly in section, showing the injection device, during an injection;

Figure 4, drawn to a larger scale, shows detail of part of the device shown in Figure 3;

Figure 5 is a perspective view, partly in section, showing the injection device, with the plunger fully depressed into the barrel;

Figure 6, drawn to a larger scale, shows detail of part of the device shown in Figure 5;

Figure 7 is a perspective view, partly in section,

CLAIMS

1. An injection device comprising an outer housing (30) adapted to receive:

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing; and

a plunger (8), axially moveable within the barrel,

wherein the injection device further comprises:

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7), characterised in that the inner housing (7) is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags (7B) in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags (7A) in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

2. The injection device of claim 1 inside which is located

said barrel for holding a volume of a medicament;

said needle (10) at one end of the barrel; and

said plunger (8), axially moveable within the barrel.

3. An injection device as claimed in claim 1 or claim 2 further comprising a spring housing (41) intermediate the outer housing (30) and the inner housing (7).

4. An injection device as claimed in any of the preceding claims wherein one or more of said tags is located at the end of a resiliently flexible leg.

5. An injection device as claimed in any of the preceding claims wherein one or more of said tags are situated at the rear end of the inner housing and are moveable radially into and out of communication with the plunger.

6. An injection device as claimed in any of claims 3-5 wherein said tags are biased radially inwardly into communication with said plunger, preferably by communication with said spring housing.

7. An injection device as claimed in any of the preceding claims wherein said tags are stored in their relaxed condition, before initiating an injection.

8. An injection device as claimed in any of claims 3-7 wherein each rear tag is moveable out of communication with the plunger when aligned with a

corresponding recess in the spring housing.

9. An injection device as claimed in any of the preceding claims wherein each rear tag is substantially T-shaped.

10. An injection device as claimed in any of claims 1-4 wherein one or more of said tags are situated at the forward end of the inner housing and are moveable radially into and out of communication with the barrel.

11. An injection device as claimed in claim 10 wherein said forward tags are biased radially inwardly into communication with said barrel, preferably by communication with said spring housing.

12. An injection device as claimed in claim 10 or claim 11 wherein said forward tags are stored in their relaxed condition, before initiating an injection.

13. An injection device as claimed in any of claims 10-12 wherein each forward tag is moveable out of communication with the barrel when aligned with a corresponding recess in the spring housing.

14. An injection device as claimed in any of claims 10-13 wherein each forward tag is substantially L-shaped.

15. An injection device as claimed in any of the preceding claims wherein said energy source is a compressed gas.

16. An injection device as claimed in any of claims 1-14 wherein said energy source is a spring.

17. An injection device as claimed in any of the preceding claims further including means for allowing the inner housing to move axially only forward with respect to the outer housing.

18. An injection device as claimed in claim 17 wherein said means is an arrangement of serrations, barbs, ratchet teeth or the like intermediate the housings.

19. An injection device as claimed in any of the preceding claims further comprising guide means for guiding, in use, the relative axial movement of the spring and outer housings, the guide means preferably comprising one or more protrusions on said spring housing which, in use, cooperate with corresponding recesses on an interior surface of said outer housing.

20. An injection device as claimed in any of the preceding claims wherein said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer and/or spring housing.

21. An injection device as claimed in any of the preceding claims wherein the needle is removable from said device.

22. An injection device as claimed in any of the preceding claims wherein said needle, barrel and plunger are removable from said device.

23. An injection device as claimed in any of the preceding claims further including a removable needle cover which protects the needle during storage before use.

24. An injection device as claimed in claim 23 wherein said needle cover includes means for pulling a protective rubber sheath or the like from said needle when said needle cover is removed from the device.

25. An injection device as claimed in claim 24 wherein said pulling means includes a floating rivet intermediate the needle cover and the protective rubber sheath or the like, whereby twisting forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

26. An injection device as claimed in any of claims 23-25 wherein the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

27. An injection device as claimed in any of the preceding claims further comprising a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place.

28. An injection device as claimed in claim 27 wherein, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

29. An injection device as claimed in any of the preceding claims further comprising means for emitting an audible and/or physical indication to a user that the injection is complete.

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Application No.	Ref.	Date
05 701 985.3 - 2310	P103497EP	30.10.2006
Applicant: The Medical House Plc		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).

Reinbold, Sylvie
Primary Examiner
for the Examining Division

Enclosure(s): 3 page/s reasons (Form 2906)

Registered Letter
EPO Form 2001 07.02CSX

The examination is being carried out on the **following application documents**:

Description, Pages

1, 3-26 as published

2, 2a filed with entry into the regional phase before the EPO

Claims, Numbers

1-29, 30(part) as published

30(part), 31 filed with entry into the regional phase before the EPO

Drawings, Sheets

1/27-27/27 as published

1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:
   D1: US-B1-6 544 234
   D2: WO 03/097133
   D3: US-A-5 681 291
   D4: WO 00/09186

Clarity Article 84 EPC

2. Although **claims 1,29 and 30** have been drafted as separate **independent claims**, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack consistencies.
   Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. (Article 84 EPC)
   Furthermore, the present set of claims does not meet the requirements of Rule 29(2)

EPC.

Failing to provide a single independent claim with the next letter of reply will result in a refusal of the application according to Article 97(1) EPC.

Further comments

3. The features of the claims should be provided with **reference signs** placed in parentheses to increase the intelligibility of the claims (Rule 29(7) EPC). This applies to both the preamble and characterising portion (see the Guidelines, C-III, 4.11).

4. Independent claim 1 is not in the **two-part form** in accordance with Rule 29(1) EPC, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 29(1)(a) EPC) and with the remaining features being included in the characterising part (Rule 29(1)(b) EPC).

5. To meet the requirements of Rule 27(1)(b) EPC, the **documents D1-D2** should be identified in the **description** and the relevant background art disclosed therein should be briefly discussed.

6. The technical feature of the inner housing is moveable between three positions, namely:
   - a second position in which the inner housing has one or more radially flexible tags which are in communication with the plunger but not the barrel
   - a third position in which said one or more radially flexible tags on the inner housing are in communication with neither the barrel nor the barrel

   seems to be inventive.
   In order to able to assess the question of the inventive step, the applicant is asked to indicate in the response which technical problem is solved by the characterising features of the new claim 1 compared to the closest prior art (Rule 27(1)c).

7. When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims.(Rule 27(2) EPC) Care should be taken during revision, especially of the introductory portion and any statements of problem or

advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

P.B.5818 - Patentlaan 2
2280 HV Rijswijk (ZH)
(070) 3 40 20 40
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Europäisches Patentamt	European Patent Office	Office européen des brevets
Generaldirektion 1	Directorate General 1	Direction générale 1

Stainthorpe, Vanessa Juliet
Harrison Goddard Foote,
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Sheffield S1 2JA
GRANDE BRETAGNE

EPO Customer Services
Tel.: +31 (0)70 340 45 00

Date
05.10.06

Reference	Application No./Patent No.
P103497EP	05701985.3 - 2310 PCT/GB2005000223

Applicant/Proprietor
The Medical House Plc

Notification of European publication number and information on the application of Article 67(3) EPC

The provisional protection under Article 67(1) and (2) EPC in the individual contracting states becomes effective only when the conditions referred to in Article 67(3) EPC have been fulfilled (for further details, see information brochure of the European Patent Office "National Law relating to the EPC" and additional information in the Official Journal of the European Patent Office).

A request has been made for extension of the patent to: AL HR LV MK
See Official Journal 1-2/1994 for further information on provisional protection.

Pursuant to Article 158(1) EPC the publication under Article 21 PCT of an international application for which the European Patent Office is a designated Office takes the place of the publication of a European patent application.

The bibliographic data of the above-mentioned Euro-PCT application will be published on 02.11.06 in Section I.1 of the European Patent Bulletin. The European publication number is 1715903.

In all future communications to the European Patent Office, please quote the application number plus Directorate number.

Receiving Section

Europäisches Patentamt • European Patent Office • Office européen des brevets

P.B.5818 - Patentlaan 2
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Date: 07-09-2006

Reference	Application No./Patent No.
P103497EP	05701985.3 - 2310 PCT/GB2005000223

Applicant/Proprietor
The Medical House Plc

Communication pursuant to Rules 109 and 110 EPC

(1) Amendment of application documents, especially the claims (R. 109 EPC)

The above mentioned international (Euro-PCT) application has entered the European phase, or can do so, once the necessary conditions are fulfilled.

Under Articles 28, 41 PCT, Rules 52, 78 PCT and Rule 86(2) to (4) EPC, the applicant may amend the application documents after receiving the international search report.

Whether or not he has already done so, he now has a further opportunity to file amended claims or other application documents within a non-extendable time limit of one month after notification of the present communication (R. 109 EPC).

The claims applicable on expiry of the above time limit, i.e. those filed on entry into the European phase or in response to the present communication, will form the basis for the calculation of any claims fee to be paid (see page 2) and for any supplementary search to be carried out under Article 157(2) EPC (R. 109 EPC).

-2/

Registered letter
EPO Form 1226 01.02 EUCL

(2) Claims fees under Rule 110 EPC

If the application documents on which the European grant procedure is to be based comprise more than ten claims, a claims fee shall be payable for the eleventh and each subsequent claim within the period provided for in Rule 107(1) EPC.

☑ Based on the application documents currently on file, all necessary claims fees have already been paid (or the documents do not comprise more than 10 claims).

☐ All necessary fees will be/have been debited automatically according to the automatic debit order.

☐ The claims fee due for the claims ..... to ..... were not paid within the above-mentioned period.

Any non-paid claims fee, either based on the current set of claims or on any amended claims to be filed pursuant to Rule 109 EPC (see page 1), may still be validly paid within a non-extendable period of grace of **one month** after notification of this communication.

If a payment is made for only some of the claims, it must be indicated for which claims it is intended. If a claims fee is not paid in due time, the claim concerned is deemed to be abandoned (R. 110(4) EPC).

If claims fees have already been paid, but on expiry of the above-mentioned time limit there is a new set of claims containing fewer fee-incurring claims than previously, the claims fees in excess of those due under Rule 110(2), 2nd sentence, EPC will be refunded (R. 110(3) EPC).

You are reminded that any supplementary search under Article 157(2) EPC will relate only to the last set of claims applicable on expiry of the above time limit AND will be confined to those fee-incurring claims for which fees have been paid in due time.

The fee for the eleventh and each subsequent claim is EUR 45,00.

Wicha, Michael
Receiving Section

Europäisches Patentamt • European Patent Office • Office européen des brevets

Eintritt in die europäische Phase (EPA als Bestimmungsamt oder ausgewähltes Amt)

Entry into the European phase (EPO as designated or elected Office)

Entrée dans la phase européenne (l'OEB agissant en qualité d'office désigné ou élu)

Europäische Anmeldenummer oder, falls nicht bekannt, PCT-Aktenzeichen oder PCT-Veröffentlichungsnummer	European application number, or, if not known, PCT application or publication number 05701985.3	Numéro de dépôt de la demande de brevet européen ou, à défaut, numéro de dépôt PCT ou de publication PCT
Zeichen des Anmelders oder Vertreters (max. 15 Positionen)	Applicant's or representative's reference (max. 15 spaces) P103497EP	Référence du demandeur ou du mandataire (15 caractères ou espaces au maximum)

☒ **1. Anmelder**
Die Angaben über den (die) Anmelder sind in der internationalen Veröffentlichung enthalten oder vom Internationalen Büro nach der internationalen Veröffentlichung vermerkt worden.

1. Applicant
Indications concerning the applicant(s) are contained in the international publication or recorded by the International Bureau after the international publication.

1. Demandeur
Les indications concernant le(s) demandeur(s) figurent dans la publication internationale ou ont été enregistrées par le Bureau international après la publication internationale.

☐ Änderungen, die das Internationale Büro noch nicht vermerkt hat, sind auf einem Zusatzblatt angegeben.

Changes which have not yet been recorded by the International Bureau are set out on an additional sheet.

Les changements qui n'ont pas encore été enregistrés par le Bureau international sont indiqués sur une feuille additionnelle.

EPO DG 1

Zustellanschrift
(siehe Merkblatt II, 1)

Address for correspondence
(see Notes II, 1)

25. 08. 2006

Adresse pour la correspondance
(voir notice II, 1)

(43)

2. Vertreter

Name (Nur einen Vertreter angeben, der in das europäische Patentregister eingetragen und an den zugestellt wird)

2. Representative

Name (Name **only one** representative who will be listed in the Register of European Patents and to whom notification will be made)

STAINTHORPE, Vanessa Juliet

2. Mandataire

Nom (N'indiquer **qu' un seul** mandataire, qui sera inscrit au Registre européen des brevets et auquel signification sera faite)

Geschäftsanschrift

Address of place of business

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☒ Weitere(r) Vertreter auf Zusatzblatt

Additional representative(s) on additional sheet Association No. 145

Autre(s) mandataire(s) sur une feuille additionnelle

3. Vollmacht

3. Authorisation

3. Pouvoir

☐ Einzelvollmacht ist beigefügt.

Individual authorisation is attached.

Un pouvoir spécial est joint.

☐ Allgemeine Vollmacht ist registriert unter Nummer:

General authorisation has been registered under No:

Un pouvoir général a été enregistré sous le n° :

☐ Allgemeine Vollmacht ist eingereicht, aber noch nicht registriert.

A general authorisation has been filed, but not yet registered.

Un pouvoir général a été déposé, mais n'est pas encore enregistré.

☐ Die beim EPA als PCT-Anmeldeamt eingereichte Vollmacht schließt ausdrücklich die europäische Phase ein.

The authorisation filed with the EPO as PCT receiving Office expressly includes the European phase.

Le pouvoir général déposé à l'OEB agissant en qualité d'office récepteur au titre du PCT s'applique expressément à la phase européenne.

☒ **4. Prüfungsantrag**
Hiermit wird die Prüfung der Anmeldung gemäß Art. 94 EPÜ beantragt. Die Prüfungsgebühr wird (wurde) entrichtet.

Prüfungsantrag in einer zugelassenen Nichtamtssprache (siehe Merkblatt III, 5.2) :

4. Request for examination
Examination of the application under Art. 94 EPC is hereby requested. The examination fee is being (has been, will be) paid.

Request for examination in an admissible non-EPO language (see Notes III, 5.2) :

4. Requête en examen
Il est demandé que soit examinée la demande de brevet conformément à l'art. 94 CBE. Il est (a été, sera) procédé au paiement de la taxe d'examen.

Requête en examen dans une langue non officielle autorisée (voir notice III, 5.2) :

☐ **5. Abschriften**
Zusätzliche Abschrift(en) der im ergänzenden europäischen Recherchenbericht angeführten Schriftstücke wird (werden) beantragt.

Anzahl der **zusätzlichen** Sätze von Abschriften

5. Copies
Additional copy (copies) of the documents cited in the supplementary European search report is (are) requested.

Number of **additional** sets of copies

5. Copies
Prière de fournir une ou plusieurs copies supplémentaires des documents cités dans le rapport complémentaire de recherche européenne.

Nombre de jeux **supplémentaires** de copies

6. Für das Verfahren vor dem EPA bestimmte Unterlagen

6.1 Dem Verfahren vor dem EPA als **Bestimmungsamt** (PCT I) sind folgende Unterlagen zugrunde zu legen:

☒ die vom Internationalen Büro **veröffentlichten Anmeldungsunterlagen** (mit **allen** Ansprüchen, Beschreibung und Zeichnungen), gegebenenfalls mit den geänderten Ansprüchen nach Art. 19 PCT

☐ soweit sie nicht ersetzt werden durch die beigefügten **Änderungen.**

Falls nötig, sind Klarstellungen auf einem Zusatzblatt einzureichen!

6.2 Dem Verfahren vor dem EPA als **ausgewähltem Amt** (PCT II) sind folgende Unterlagen zugrunde zu legen:

☒ die dem **internationalen vorläufigen Prüfungsbericht zugrunde gelegten Unterlagen,** einschließlich seiner eventuellen **Anlagen**
(Solche Anlagen müssen immer beigefügt werden)

☒ soweit sie nicht ersetzt werden durch die beigefügten **Änderungen.**

Falls nötig, sind Klarstellungen auf einem Zusatzblatt einzureichen!

☒ Sind dem EPA als mit der internationalen vorläufigen Prüfung beauftragten Behörde **Versuchsberichte** zugegangen, dürfen diese dem Verfahren vor dem EPA zugrunde gelegt werden.

6. Documents intended for proceedings before the EPO

6.1 Proceedings before the EPO as **designated Office** (PCT I) are to be based on the following documents:

the **application documents published** by the International Bureau (with **all** claims, description and drawings), where applicable with amended claims under Art. 19 PCT

unless replaced by the **amendments** enclosed.

Where necessary, clarifications must be submitted on a separate sheet!

6.2 Proceedings before the EPO as **elected Office** (PCT II) are to be based on the following documents:

the **documents on which the international preliminary examination report is based**, including its possible **annexes**
(Such annexes must always be filed)

unless replaced by the **amendments** enclosed.

Where necessary, clarifications must be submitted on a separate sheet!

If the EPO as International Preliminary Examining Authority has received **test reports**, these may be used as the basis of proceedings before the EPO.

6. Pièces destinées à la procédure devant l'OEB

6.1 La procédure devant l'OEB agissant en qualité **d'office désigné** (PCT I) doit se fonder sur les pièces suivantes :

les **pièces de la demande publiée** par le Bureau international (avec **toutes** les revendications, la description et les dessins), éventuellement avec les revendications modifiées conformément à l'article 19 du PCT

dans la mesure où elles ne sont pas remplacées par les **modifications** jointes.

Le cas échéant, des explications doivent être jointes sur une feuille additionnelle!

6.2 La procédure devant l'OEB **agissant en qualité d'office élu** (PCT II) doit se fonder sur les pièces suivantes :

les **pièces sur lesquelles se fonde le rapport d'examen préliminaire international**, y compris ses **annexes** éventuelles
(De telles annexes sont toujours à joindre)

dans la mesure où elles ne sont pas remplacées par les **modifications** jointes.

Le cas échéant, des explications doivent être jointes sur une feuille additionnelle!

Si l'OEB, agissant en qualité d'administration chargée de l'examen préliminaire international, a reçu des **rapports d'essais**, ceux-ci peuvent constituer la base de la procédure devant l'OEB.

7. Übersetzungen
Beigefügt sind die nachfolgend angekreuzten Übersetzungen in einer der Amtssprachen des EPA (Deutsch, Englisch, Französisch):

- *Im Verfahren vor dem EPA als* ***Bestimmungsamt oder ausgewähltem Amt*** *(PCT I + II):*

☐ Übersetzung der **ursprünglich eingereichten internationalen Anmeldung** (Beschreibung, Ansprüche, etwaige Textbestandteile in den Zeichnungen), der veröffentlichten Zusammenfassung, und etwaiger Angaben über biologisches Material nach Regel 13bis.3 und 13bis.4 PCT

☐ Übersetzung der **prioritätsbegründenden Anmeldung(en)**

☐ Es wird hiermit erklärt, daß die internationale Anmeldung in ihrer ursprünglich eingereichten Fassung eine vollständige Übersetzung der früheren Anmeldung ist (Regel 38(5) EPÜ)

- ***Zusätzlich*** *im Verfahren vor dem EPA als* ***Bestimmungsamt*** *(PCT I):*

☐ Übersetzung der nach Art. 19 PCT **geänderten Ansprüche** nebst Erklärung, falls diese dem Verfahren vor dem EPA zugrunde gelegt werden sollen (siehe Feld 6)

- ***Zusätzlich*** *im Verfahren vor dem EPA als* ***ausgewähltem Amt*** *(PCT II):*

☐ Übersetzung der **Anlagen zum internationalen vorläufigen Prüfungsbericht**

7. Translations
Translations in one of the official languages of the EPO (English, French, German) are enclosed as crossed below:

- *In proceedings before the EPO as* ***designated or elected Office*** *(PCT I + II):*

Translation of the **international application** (description, claims, any text in the drawings) **as originally filed**, of the abstract as published and of any indication under Rule 13bis.3 and 13bis.4 PCT regarding biological material

Translation of **the priority application(s)**

It is hereby declared that the international application as originally filed is a complete translation of the previous application (Rule 38(5) EPC)

- ***In addition,*** *in proceedings before the EPO as* ***designated Office*** *(PCT I):*

Translation of **amended claims** and any statement under Art. 19 PCT, if the claims as amended are to form the basis for the proceedings before the EPO (see Section 6)

- ***In addition,*** *in proceedings before the EPO as* ***elected Office*** *(PCT II):*

Translation of any **annexes to the international preliminary examination report**

7. Traductions
Vous trouverez, ci-joint, les traductions cochées ci-après dans l'une des langues officielles de l'OEB (allemand, anglais, français) :

- *Dans la procédure devant l'OEB agissant en qualité d'****office désigné ou élu*** *(PCT I + II):*

Traduction de la **demande internationale telle que déposée initialement** (description, revendications, textes figurant éventuellement dans les dessins), de l'abrégé publié, et de toutes indications visées aux règles 13bis.3 et 13bis.4 du PCT concernant le matériel biologique

Traduction de la (des) **demande(s) ouvrant le droit de priorité**

Il est déclaré par la présente que la demande internationale telle que déposée initialement est une traduction intégrale de la demande antérieure (règle 38(5) CBE)

- ***De plus,*** *dans la procédure devant l'OEB agissant en qualité d'****office désigné*** *(PCT I) :*

Traduction des **revendications modifiées** et de la déclaration faite conformément à l'article 19 du PCT, si la procédure devant l'OEB doit être fondée sur les revendications modifiées (voir la rubrique 6)

- ***De plus,*** *dans la procédure devant l'OEB agissant en qualité d'****office élu*** *(PCT II) :*

Traduction des **annexes du rapport d'examen préliminaire international**

☐ **8. Biologisches Material**
Die Erfindung bezieht sich auf bzw. verwendet biologisches Material, das nach Regel 28 EPÜ hinterlegt worden ist.

☐ Die **Angaben nach Regel 28(1)c) EPÜ** (falls noch nicht bekannt, die Hinterlegungsstelle und das (die) Bezugszeichen [Nummer, Symbole usw.] des Hinterlegers) sind in der internationalen Veröffentlichung oder in der gemäß Feld 7 eingereichten Übersetzung enthalten auf:

Seite(n) / Zeile(n)

Die **Empfangsbescheinigung(en)** der Hinterlegungsstelle

☐ ist (sind) beigefügt

☐ wird (werden) nachgereicht

☐ Verzicht auf die Verpflichtung des Antragstellers nach Regel 28(3) EPÜ auf gesondertem Schriftstück

8. Biological material
The invention relates to and/or uses biological material deposited under Rule 28 EPC.

The particulars referred to in Rule 28(1)(c) EPC (if not yet known, the depository institution and the identification reference(s) [number, symbols etc.] of the depositor) are given in the international publication or in the translation submitted under Section 7 on:

page(s) / line(s)

The **receipt(s) of deposit** issued by the depositary institution

is (are) enclosed

will be filed at a later date

Waiver of the right to an undertaking from the requester pursuant to Rule 28(3) EPC attached.

8. Matière biologique
L'invention concerne et/ou utilise de la matière biologique, déposée conformément à la règle 28 CBE.

Les **indications visées à la règle 28(1)c) CBE** (si non encore connues, l'autorité de dépôt et la (les) référence(s) d'identification [numéro ou symboles etc.] du déposant) figurent dans la publication internationale ou dans une traduction produite conformément à la rubrique 7 à la / aux:

page(s) / ligne(s)

Le(s) **récépissé(s) de dépôt** délivré(s) par l'autorité de dépôt

est (sont) joint(s)

sera (seront) produit(s) ultérieurement

Renonciation, sur document distinct, à l'engagement du requérant au titre de la règle 28(3) CBE.

9. Nucleotid- und Aminosäuresequenzen

☐ Die nach Regeln 5.2 und 13ter PCT sowie Regel 111(3) EPÜ erforderlichen Unterlagen liegen dem EPA bereits vor.

☐ Das schriftliche Sequenzprotokoll wird anliegend nachgereicht.

☐ Das Sequenzprotokoll geht nicht über den Inhalt der Anmeldung in der ursprünglich eingereichten Fassung hinaus.

☐ Der vorgeschriebene Datenträger ist beigefügt.

☐ Die auf dem Datenträger gespeicherte Information stimmt mit dem schriftlichen Sequenzprotokoll überein.

9. Nucleotide and amino acid sequences

The items necessary in accordance with Rules 5.2 and 13ter PCT and Rule 111(3) EPC have already been furnished to the EPO.

The written sequence listing is furnished herewith.

The sequence listing does not include matter which goes beyond the content of the application as filed.

The prescribed data carrier is enclosed.

The information recorded on the data carrier is identical to the written sequence listing.

9. Séquences de nucléotides et d'acides aminés

Les pièces requises selon les règles 5.2 et 13ter PCT et la règle 111(3) CBE ont déjà été déposées auprès de l'OEB.

La liste de séquences écrite est produite ci-joint.

La liste de séquences ne contient pas d'éléments s'étendant au-delà du contenu de la demande telle qu'elle a été déposée.

Le support de données prescrit est joint.

L'information figurant sur le support de données est identique à celle que contient la liste de séquences écrite.

10. Benennungsgebühren

☒ 10.1 Es ist derzeit beabsichtigt, den **siebenfachen** Betrag einer Benennungsgebühr zu entrichten. Damit gelten die Benennungsgebühren für **alle Vertragsstaaten des EPÜ**[1] als entrichtet (Art. 2 Nr. 3 GebO), soweit sie **in der internationalen Anmeldung** bestimmt sind[2].

☐ 10.2 Abweichend von der Erklärung in Nr. 10.1 ist derzeit beabsichtigt, **weniger als sieben** Benennungsgebühren für folgende **in der internationalen Anmeldung bestimmte Vertragsstaaten des EPÜ**[2] zu entrichten:

(1) ☐ _____ (4) ☐ _____

(2) ☐ _____ (5) ☐ _____

(3) ☐ _____ (6) ☐ _____

Soweit unter Nr. 10.2 Vertragsstaaten aufgeführt sind, wird beantragt, für die dort nicht aufgeführten Vertragsstaaten von der Zustellung einer Mitteilung nach Regel 108(3) EPÜ abzusehen.

☒ 10.3 Wird ein **automatischer Abbuchungsauftrag** erteilt (Feld 12), so wird das EPA beauftragt, bei Ablauf der Grundfrist nach Regel 107 (1)d) EPÜ den siebenfachen Betrag einer Benennungsgebühr abzubuchen. Ist eine Erklärung nach Nr. 10.2 abgegeben worden, so sollen die Benennungsgebühren nur für die dort angegebenen Vertragsstaaten abgebucht werden, sofern dem EPA nicht bis zum Ablauf der Grundfrist ein anderslautender Auftrag zugeht.

10. Designation fees

10.1 It is currently intended to pay **seven times** the amount of the designation fee. The designation fees for **all the EPC contracting states**[1] **designated in the international application**[2] are thereby deemed to have been paid (Art. 2 No. 3 RFees).

10.2 The declaration in No. 10.1 does not apply. Instead, it is currently intended to pay **fewer than seven** designation fees for the following **EPC contracting states**[2] **designated in the international application**:

If contracting states are indicated under No. 10.2, it is requested that no communication under Rule 108(3) EPC be issued for contracting states not thus indicated.

10.3 If an **automatic debit order** has been issued (Section 12), the EPO is authorised, on expiry of the basic period under Rule 107(1)(d) EPC, to debit seven times the amount of the designation fee. If states are indicated under No. 10.2, the EPO will debit designation fees only for those states, unless instructed otherwise before the basic period expires.

10. Taxes de désignation

10.1 Il est actuellement envisagé de payer un montant correspondant à **sept fois** la taxe de désignation. Les taxes de désignation sont ainsi réputées payées pour **tous les Etats contractants de la CBE**[1] **désignés dans la demande internationale**[2] (art. 2, point 3 du RRT).

10.2 Contrairement à ce qui est indiqué au n° 10.1, il est actuellement envisagé de payer **moins de sept** taxes de désignation pour les **Etats contractants de la CBE**[2] suivants **désignés dans la demande internationale** :

Si des Etats contractants sont mentionnés au n° 10.2, prière de ne pas procéder à la signification d'une notification prévue par la règle 108(3) CBE pour les Etats contractants n'y étant pas mentionnés.

10.3 Si un **ordre de prélèvement automatique** est donné (rubrique 12), il est demandé à l'OEB de prélever, à l'expiration du délai normal visé à la règle 107(1)d) CBE, un montant correspondant à sept fois la taxe de désignation. Si une déclaration a été faite au n° 10.2, les taxes de désignation ne sont à prélever que pour les Etats contractants qui y sont indiqués, sauf instruction contraire reçue par l'OEB avant l'expiration du délai normal.

1 Stand bei Drucklegung: 27 Vertragsstaaten, und zwar: / Status when this form was printed: 27 contracting states, namely / Situation à la date d'impression : 27 Etats contractants, à savoir : AT Österreich / Austria / Autriche, BE Belgien / Belgium / Belgique, BG Bulgarien / Bulgaria / Bulgarie, CH / LI Schweiz und Liechtenstein / Switzerland and Liechtenstein / Suisse et Liechtenstein, CY Zypern / Cyprus / Chypre, CZ Tschechische Republik / Czech Republic / République tchèque, DE Deutschland / Germany / Allemagne, DK Dänemark / Denmark / Danemark, EE Estland / Estonia / Estonie, ES Spanien / Spain / Espagne, FI Finnland / Finland / Finlande, FR Frankreich / France / France, GB Vereinigtes Königreich / United Kingdom / Royaume-Uni, GR Griechenland / Greece / Grèce, HU Ungarn / Hungary / Hongrie, IE Irland / Ireland / Irlande, IT Italien / Italy / Italie, LU Luxemburg / Luxembourg / Luxembourg, MC Monaco / Monaco / Monaco, NL Niederlande / Netherlands / Pays-Bas, PT Portugal / Portugal / Portugal, RO Rumänien / Romania / Roumanie, SE Schweden / Sweden / Suède, SI Slowenien / Slovenia / Slovénie, SK Slowakische Republik / Slovak Republic / République slovaque, TR Türkei / Turkey / Turquie

2 Für folgende Staaten nur möglich, falls in der internationalen Anmeldung am oder nach folgendem Tag bestimmt: Slowakische Republik, Bulgarien, Tschechische Republik und Estland: 1. Juli 2002, Slowenien: 1. Dezember 2002, Ungarn: 1. Januar 2003 und Rumänien: 1. März 2003. / For the following states this is possible only if they are designated in the international application on or after the stated date: Slovak Republic, Bulgaria, Czech Republic and Estonia: 1 July 2002, Slovenia: 1 December 2002, Hungary: 1 January 2003 and Romania: 1 March 2003. / En ce qui concerne les Etats suivants seulement si la désignation a été effectuée dans la demande internationale à la date suivante ou à une date ultérieure: République slovaque, Bulgarie, République tchèque et Estonie: 1er juillet 2002, Slovénie: 1er décembre 2002, Hongrie: 1er janvier 2003 et Roumanie: 1er mars 2003.

☒ **11. Erstreckung des europäischen Patents**
Bei Zahlung der Erstreckungsgebühr(en) gilt diese Anmeldung auch als wirksamer Erstreckungsantrag für die in der internationalen Anmeldung bestimmten »Erstreckungsstaaten«. Es ist beabsichtigt, diese Gebühr(en) für folgende Staaten zu entrichten:

11. Extension of the European patent
On payment of the extension fee(s) this application is also deemed to be a request for extension to all the "extension states" designated in the international application. It is intended to pay the fee(s) for the following states:

11. Extension des effets du brevet européen
La taxe (Les taxes) d'extension payée(s), la présente demande est également réputée être une demande d'extension à tous les «Etats autorisant l'extension» désignés dans la demande internationale. Il est envisagé de payer la taxe (les taxes) d'extension pour les Etats suivants:

☐	SI	Slowenien [1]	Slovenia [1]	Slovénie [1]
☐	LT	Litauen	Lithuania	Lituanie
☒	LV	Lettland	Latvia	Lettonie
☒	AL	Albanien	Albania	Albanie
☐	RO	Rumänien [1]	Romania [1]	Roumanie [1]
☒	MK	Ehemalige jugoslawische Republik Mazedonien	Former Yugoslav Republic of Macedonia	Ex-République yougoslave de Macédoine
☒	HR	Croatia [2]	BA Bosnia & Herzegovina [2]	YU Serbia & Montenegro [2]

1) Für Slowenien und Rumänien nur möglich, falls in der internationalen Anmeldung bis 30. November 2002 (Slowenien) oder bis 28. Februar 2003 (Rumänien) bestimmt. / For Slovenia and Romania this is possible only if they are designated in the international application up to 30 November 2002 (Slovenia) or 28 February 2003 (Romania). / En ce qui concerne la Slovénie et la Roumanie, seulement si la désignation a été effectuée dans la demande internationale jusqu'au 30 novembre 2002 (Slovénie) ou jusqu'au 28 février 2003 (Roumanie).

2) Platz für Staaten, mit denen »Erstreckungsabkommen« nach Drucklegung dieses Formblatts in Kraft treten und die in der internationalen Anmeldung bestimmt waren. / Space for States with which "extension agreements" enter into force after this form has been printed and which were designated in the international application. / Prévu pour des Etats à l'égard desquels des «accords d'extension» entreront en vigueur après l'impression du présent formulaire et qui ont été désignés dans la demande internationale.

12. Automatischer Abbuchungsauftrag ***(Nur möglich für Inhaber von beim EPA geführten laufenden Konten)***

☐ Das EPA wird beauftragt, nach Maßgabe der Vorschriften über das automatische Abbuchungsverfahren fällige Gebühren und Auslagen vom untenstehenden laufenden Konto abzubuchen. In Bezug auf die **Benennungsgebühren** wird auf Feld 10.3 verwiesen. Das EPA wird ferner beauftragt, die **Erstreckungsgebühren** für jeden in Feld 11 angekreuzten »Erstreckungsstaat« bei Ablauf der Grundfrist zu ihrer Zahlung abzubuchen, sofern ihm nicht bis dahin ein anderslautender Auftrag zugeht.

Nummer und Kontoinhaber

12. Automatic debit order ***(for EPO deposit account holders only)***

The EPO is hereby authorised, under the Arrangements for the automatic debiting procedure, to debit from the deposit account below any fees and costs falling due. For **designation fees**, see Section 10.3. The EPO is also authorised, on expiry of the basic period for paying the **extension fees**, to debit those fees for each of the "extension states" marked with a cross in Section 11, unless instructed otherwise before the said period expires.

Number and account holder

12. Ordre de prélèvement automatique ***(uniquement possible pour les titulaires de comptes courants ouverts auprès de l'OEB)***

Par la présente, il est demandé à l'OEB de prélever du compte courant ci-dessous les taxes et frais venant à échéance, conformément à la réglementation relative au prélèvement automatique. Pour les **taxes de désignation,** se reporter à la rubrique 10.3. Il est en outre demandé à l'OEB de prélever, à l'expiration du délai normal prévu pour leur paiement, les **taxes d'extension** pour chaque «Etat autorisant l'extension» coché à la rubrique 11, sauf instruction contraire reçue avant l'expiration de ce délai.

Numéro et titulaire du compte

☒ **13.** Eventuelle **Rückzahlungen** auf das beim EPA geführte laufende Konto

Nummer und Kontoinhaber

13. Any **reimbursement** to EPO deposit account

Number and account holder

Harrison Goddard Foote - 28050228

13. Remboursements éventuels à effectuer sur le compte courant ouvert auprès de l'OEB

Numéro et titulaire du compte

14. Unterschrift(en) des (der) Anmelder(s) oder Vertreters

Ort / Datum

Für Angestellte (Art. 133(3) EPÜ) mit allgemeiner Vollmacht:

Nr.

Name(n) des (der) Unterzeichneten bitte in Druckschrift wiederholen. Bei juristischen Personen bitte auch die Stellung des (der) Unterzeichneten innerhalb der Gesellschaft in Druckschrift angeben.

14. Signature(s) of applicant(s) or representative

STAINTHORPE, Vanessa Juliet

Place / Date 22.08.2006, Sheffield, UK

For employees (Art. 133(3) EPC) having a general authorisation:

No.

Please print name(s) under signature(s). In the case of legal persons, the position of the signatory within the company should also be printed.

14. Signature(s) du (des) demandeur(s) ou du mandataire

Lieu / Date

Pour les employés (art. 133(3) CBE) disposant d'un pouvoir général :

N°

Le ou les noms des signataires doivent être indiqués en caractères d'imprimerie. S'il s'agit d'une personne morale, la position occupée au sein de celle-ci par le ou les signataires doit également être indiquée en caractères d'imprimerie.

ADDITIONAL REPRESENTATIVES – ASSOCIATION NO. 145

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Balm Green
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Attorneys

FAXED

22 August 2006

EPO - DG 1

25. 08. 2006

(43)

European Patent Office
PB 5818 Patentlaan 2
2280 HV RIJSWIJK (ZH)
Netherlands

Your ref: 05701985.3-2310
Our ref: VJS/P103497EP

By Fax: 0031 70 340 30 16
Sender: Vanessa Stainthorpe
Pages: 16 inc this page

Dear Sirs

European Patent Application No. 05701985.3
Regional Phase of International Patent Application No PCT/GB2005/000223
Auto Safety Injector
The Medical House plc

I enclose herewith documents for proceeding with the regional phase of the above PCT patent application in the European Patent Office, designating all available states and extension states.

Replacement pages 2 and 2a of the description are enclosed, on which prior art document D1 has been identified and discussed. Replacement page 33 of the claims is enclosed on which original claim 32 has been deleted. Therefore claims 1-31, as attached to the International Preliminary Report on Patentability are currently pending in the application. The applicant reserves the right to file a divisional application for any of the subject matter contained in the original application as filed.

Also enclosed are copies of EPO Form 1037, and I should be grateful if you would stamp and return one of these to me immediately, as an acknowledgement of receipt of the above documents.

You are authorised to deduct the necessary fees for the filing of this application from our deposit account

Fountain Precinct, Balm Green
Sheffield S1 2JA UK
Tel: +44(0) 114 274 3700
Fax: +44(0) 114 273 0312
Email: vstainthorpe@hgf.com

no. 28050228, and to make up the difference should, for any reason, the fees have been understated on the fee schedule.

Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote – Association No 145

the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing inside which is located

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing is in communication with both the plunger and the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which the inner housing is in communication with neither the plunger nor the barrel

the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing inside which is located

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source between three positions, namely

a plunger, axially moveable within the barrel, wherein the injection device further comprises:

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

characterised in that the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

31. An injection device as claimed in claim 29 or claim 30 having all of the features of any of claims 2-28.

a plunger, axially moveable within the barrel, wherein the injection device further comprises:

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

characterised in that the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

31. An injection device as claimed in claim 29 or claim 30 having all of the features of any of claims 2-28.

~~32. An injection device substantially as described herein with reference to and as illustrated in any appropriate combination of the accompanying drawings.~~

Payment of fees and costs

Zur Kasse

European Patent Office
Treasury and Accounts Directorate
D - 80298 München
Fax: (+49-89) 2399 - 2528

Please complete in typescript only

01 Name of payer: Harrison Goddard Foote

Payer's reference: VJS/AC/P103497EP

02 Address: Harrison Goddard Foote, Fountain Precinct, Balm Green, SHEFFIELD, S1 2JA

Mode of payment:
- ☐ Bank/Giro transfer [1]
- ☐ Enclosed Cheque No.
- ☒ Debit from deposit account with the EPO is requested [2]

Bank/Giro Office:

Deposit account No.: 28050228

03 Patent application / Patent No. (A separate form is required for each application)

EP 05701985.3 PCT /GB2005/000223 03

	Code		Currency	Amount
04	001	Filing fee	EUR	
05	002	Search fee	EUR	
06	005	Designation fee(s) [3]	EUR	560.00
07	015	Claims fee(s) (Rule 31(1) EPC)	EUR	945.00
08	055	Additional copy	EUR	
09	006	Examination fee	EUR	745.00
10	007	Fee for grant including fee for printing (up to 35 pages)	EUR	
11	008	Additional fee for printing (more than 35 pages)	EUR	
12	033	Renewal fee for the 3rd year	EUR	
13	034	Renewal fee for the 4th year	EUR	
14	035	Renewal fee for the 5th year	EUR	
15	403	Extension fee(s) for [4]: Latvia	EUR	102.00
16	404	Albania	EUR	102.00
17	406	Macedonia	EUR	102.00
18	407	Croatia	EUR	102.00
19	408	Bosnia and Herzegovina	EUR	102.00
20	409	Serbia and Montenegro	EUR	102.00
21	020	National Basic Fee	EUR	170.00
22		Total	EUR	3,032.00

Signature: Vanessa J Stainthorpe

Place, Date: Sheffield, GB 22/08/2006

HGF
Harrison Goddard Foote
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Attorneys

22 August 2006

European Patent Office
PB 5818 Patentlaan 2
2280 HV RIJSWIJK (ZH)
Netherlands

Your ref: 05701985.3-2310
Our ref: VJS/P103497EP

By Fax: 0031 70 340 30 16
Sender: Vanessa Stainthorpe
Pages: 16 inc this page

Dear Sirs

European Patent Application No. 05701985.3
Regional Phase of International Patent Application No PCT/GB2005/000223
Auto Safety Injector
The Medical House plc

I enclose herewith documents for proceeding with the regional phase of the above PCT patent application in the European Patent Office, designating all available states and extension states.

Replacement pages 2 and 2a of the description are enclosed, on which prior art document D1 has been identified and discussed. Replacement page 33 of the claims is enclosed on which original claim 32 has been deleted. Therefore claims 1-31, as attached to the International Preliminary Report on Patentability are currently pending in the application. The applicant reserves the right to file a divisional application for any of the subject matter contained in the original application as filed.

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You are authorised to deduct the necessary fees for the filing of this application from our deposit account

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www.hgf.com

no. 28050228, and to make up the difference should, for any reason, the fees have been understated on the fee schedule.

Yours faithfully

Vanessa Stainthorpe
European Patent Attorney
For and on behalf of Harrison Goddard Foote – Association No 145

Posted

Europäisches Patentamt | European Patent Office | Office européen des brevets

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D-10958 Berlin
(+49-30) 25901-0
Fax (+49-30) 25901-840

68

Bestätigung über den Eingang nachgereichter Unterlagen für Patentanmeldungen/Patente beim Europäischen Patentamt

Datum und Ort des Eingangs sind aus der Perforation dieser Eingangsbestätigung ersichtlich
(M + Datum = Einreichungsort München; H + Datum = Einreichungsort Den Haag; Datum + B = Einreichungsort Berlin)

Acknowledgement of receipt for subsequently filed items relating to patent applications/patents at the European Patent Office

Date and place of receipt are shown by the perforation appearing on this receipt

(M + date = Munich as place of receipt; H + date = The Hague as place of receipt; date + B = Berlin as place of receipt)

Accusé de réception à l'Office européen des brevets de pièces produites postérieurement au dépôt d'une demande de brevet/ à la délivrance d'un brevet européen

La date et le lieu de réception sont indiqués par la perforation du présent accusé de réception
(M + date = pièces reçues à Munich; H + date = pièces reçues à La Haye; date + B = pièces reçues à Berlin)

Eingereichte Unterlagen	Items filed	Pièces envoyées
Anmeldungs- (und Direktions-*) Nr./Patent Nr. Application (and Directorate*) No./Patent No. N° de la demande (et de la direction*)/n° du brevet	Ihr Zeichen Your reference Votre référence	ggfs. Art und Datum der Unterlagen** Nature and date of items (optional)** Nature et date des pièces (facultatif)**
1 05701985.3	P103497EP	Faxed letter of 22 August 2006
2	The Medical House plc	EPO Form 1200
3		EPO Form 1010
4		Replacement pgs 2, 2a and 33
5		
6		
7		
8		
9		
10		

* falls bereits bekannt

** Der Eingang der angegebenen Unterlagen wird bestätigt.
Enthält diese Spalte keine Eintragungen, so wird lediglich bestätigt, daß eine Sendung zu dem angegebenen Aktenzeichen eingegangen ist.

* if already known

** The receipt of the items indicated is confirmed.
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* si déjà connu

** La réception des pièces indiquées est confirmée.
Faute de mention dans cette colonne, le présent accusé de réception se rapporte à une pièce quelconque envoyée sous la référence indiquée.

EPA/EPO/OEB Form 1037.1 03.99
Eingangsbestätigung für Einsender
Acknowledgement of receipt for sender
Accusé de réception expéditeur

Europäisches Patentamt | European Patent Office | Office européen des brevets

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Tx 31 651 epo nl
Fax (+31-70) 340-3016

D-10958 Berlin
(+49-30) 25901-0
Fax (+49-30) 25901-840

68

Bestätigung über den Eingang nachgereichter Unterlagen für Patentanmeldungen/Patente beim Europäischen Patentamt

Datum und Ort des Eingangs sind aus der Perforation dieser Eingangsbestätigung ersichtlich
(M + Datum = Einreichungsort München;
H + Datum = Einreichungsort Den Haag;
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Accusé de réception à l'Office européen des brevets de pièces produites postérieurement au dépôt d'une demande de brevet/ à la délivrance d'un brevet européen

La date et le lieu de réception sont indiqués par la perforation du présent accusé de réception
(M + date = pièces reçues à Munich;
H + date = pièces reçues à La Haye;
date + B = pièces reçues à Berlin)

Eingereichte Unterlagen Anmeldungs- (und Direktions-*) Nr./Patent Nr. Application (and Directorate*) No./Patent No. N° de la demande (et de la direction*)/n° du brevet	Items filed Ihr Zeichen Your reference Votre référence	Pièces envoyées ggfs. Art und Datum der Unterlagen** Nature and date of items (optional)** Nature et date des pièces (facultatif)**
1 05701985.3	P103497EP	Faxed letter of 22 August 2006
2	The Medical House plc	EPO Form 1200
3		EPO Form 1010
4		Replacement pgs 2, 2a and 33
5		
6		
7		
8		
9		
10		

* falls bereits bekannt

** Der Eingang der angegebenen Unterlagen wird bestätigt.
Enthält diese Spalte keine Eintragungen, so wird lediglich bestätigt, daß eine Sendung zu dem angegebenen Aktenzeichen eingegangen ist.

* If already known

** The receipt of the items indicated is confirmed.
If this column does not contain any entries, it is only confirmed that an item has been received for the indicated file.

* si déjà connu

** La réception des pièces indiquées est confirmée.
Faute de mention dans cette colonne, le présent accusé de réception se rapporte à une pièce quelconque envoyée sous la référence indiquée.

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An das Europäische Patentamt | To the European Patent Office | A l'Office européen des brevets 1

Eintritt in die europäische Phase (EPA als Bestimmungsamt oder ausgewähltes Amt)

Entry into the European phase (EPO as designated or elected Office)

Entrée dans la phase européenne (l'OEB agissant en qualité d'office désigné ou élu)

Europäische Anmeldenummer oder, falls nicht bekannt, PCT-Aktenzeichen oder PCT-Veröffentlichungsnummer	European application number, or, if not known, PCT application or publication number 05701985.3	Numéro de dépôt de la demande de brevet européen ou, à défaut, numéro de dépôt PCT ou de publication PCT
Zeichen des Anmelders oder Vertreters (max. 15 Positionen)	Applicant's or representative's reference (max. 15 spaces) P103497EP	Référence du demandeur ou du mandataire (15 caractères ou espaces au maximum)

☒ **1. Anmelder**
Die Angaben über den (die) Anmelder sind in der internationalen Veröffentlichung enthalten oder vom Internationalen Büro nach der internationalen Veröffentlichung vermerkt worden.

1. Applicant
Indications concerning the applicant(s) are contained in the international publication or recorded by the International Bureau after the international publication.

1. Demandeur
Les indications concernant le(s) demandeur(s) figurent dans la publication internationale ou ont été enregistrées par le Bureau international après la publication internationale.

☐ Änderungen, die das Internationale Büro noch nicht vermerkt hat, sind auf einem Zusatzblatt angegeben.

Changes which have not yet been recorded by the International Bureau are set out on an additional sheet.

Les changements qui n'ont pas encore été enregistrés par le Bureau international sont indiqués sur une feuille additionnelle.

Zustellanschrift
(siehe Merkblatt II, 1)

Address for correspondence
(see Notes II, 1)

Adresse pour la correspondance
(voir notice II, 1)

2. Vertreter

Name (**Nur einen** Vertreter angeben, der in das europäische Patentregister eingetragen und an den zugestellt wird)

2. Representative

Name (Name **only one** representative who will be listed in the Register of European Patents and to whom notification will be made)

STAINTHORPE, Vanessa Juliet

2. Mandataire

Nom (N'indiquer **qu'un seul** mandataire, qui sera inscrit au Registre européen des brevets et auquel signification sera faite)

Geschäftsanschrift

Address of place of business

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☒ Weitere(r) Vertreter auf Zusatzblatt

Additional representative(s) on additional sheet Association No. 145

Autre(s) mandataire(s) sur une feuille additionnelle

3. Vollmacht

3. Authorisation

3. Pouvoir

☐ Einzelvollmacht ist beigefügt.

Individual authorisation is attached.

Un pouvoir spécial est joint.

☐ Allgemeine Vollmacht ist registriert unter Nummer:

General authorisation has been registered under No:

Un pouvoir général a été enregistré sous le n° :

☐ Allgemeine Vollmacht ist eingereicht, aber noch nicht registriert.

A general authorisation has been filed, but not yet registered.

Un pouvoir général a été déposé, mais n'est pas encore enregistré.

☐ Die beim EPA als PCT-Anmeldeamt eingereichte Vollmacht schließt ausdrücklich die europäische Phase ein.

The authorisation filed with the EPO as PCT receiving Office expressly includes the European phase.

Le pouvoir général déposé à l'OEB agissant en qualité d'office récepteur au titre du PCT s'applique expressément à la phase européenne.

☒ **4. Prüfungsantrag**
Hiermit wird die Prüfung der Anmeldung gemäß Art. 94 EPÜ beantragt. Die Prüfungsgebühr wird (wurde) entrichtet.

Prüfungsantrag in einer zugelassenen Nichtamtssprache (siehe Merkblatt III, 5.2) :

4. Request for examination
Examination of the application under Art. 94 EPC is hereby requested. The examination fee is being (has been, will be) paid.

Request for examination in an admissible non-EPO language (see Notes III, 5.2) :

4. Requête en examen
Il est demandé que soit examinée la demande de brevet conformément à l'art. 94 CBE. Il est (a été, sera) procédé au paiement de la taxe d'examen.

Requête en examen dans une langue non officielle autorisée (voir notice III, 5.2) :

☐ **5. Abschriften**
Zusätzliche Abschrift(en) der im ergänzenden europäischen Recherchenbericht angeführten Schriftstücke wird (werden) beantragt.

Anzahl der **zusätzlichen** Sätze von Abschriften

5. Copies
Additional copy (copies) of the documents cited in the supplementary European search report is (are) requested.

Number of **additional** sets of copies

5. Copies
Prière de fournir une ou plusieurs copies supplémentaires des documents cités dans le rapport complémentaire de recherche européenne.

Nombre de jeux **supplémentaires** de copies

6. Für das Verfahren vor dem EPA bestimmte Unterlagen

6.1 Dem Verfahren vor dem EPA als **Bestimmungsamt** (PCT I) sind folgende Unterlagen zugrunde zu legen:

☒ die vom Internationalen Büro **veröffentlichten Anmeldungsunterlagen** (mit **allen** Ansprüchen, Beschreibung und Zeichnungen), gegebenenfalls mit den geänderten Ansprüchen nach Art. 19 PCT

☐ soweit sie nicht ersetzt werden durch die beigefügten **Änderungen.**

Falls nötig, sind Klarstellungen auf einem Zusatzblatt einzureichen!

6. Documents intended for proceedings before the EPO

6.1 Proceedings before the EPO as **designated Office** (PCT I) are to be based on the following documents:

the application documents published by the International Bureau (with **all** claims, description and drawings), where applicable with amended claims under Art. 19 PCT

unless replaced by the **amendments** enclosed.

Where necessary, clarifications must be submitted on a separate sheet!

6. Pièces destinées à la procédure devant l'OEB

6.1 La procédure devant l'OEB agissant en qualité **d'office désigné** (PCT I) doit se fonder sur les pièces suivantes :

les pièces de la demande publiée par le Bureau international (avec **toutes** les revendications, la description et les dessins), éventuellement avec les revendications modifiées conformément à l'article 19 du PCT

dans la mesure où elles ne sont pas remplacées par les **modifications** jointes.

Le cas échéant, des explications doivent être jointes sur une feuille additionnelle!

6.2 Dem Verfahren vor dem EPA als **ausgewähltem Amt** (PCT II) sind folgende Unterlagen zugrunde zu legen:

☒ die dem **internationalen vorläufigen Prüfungsbericht zugrunde gelegten Unterlagen,** einschließlich seiner eventuellen **Anlagen**
(Solche Anlagen müssen immer beigefügt werden)

☒ soweit sie nicht ersetzt werden durch die beigefügten **Änderungen.**

Falls nötig, sind Klarstellungen auf einem Zusatzblatt einzureichen!

☒ Sind dem EPA als mit der internationalen vorläufigen Prüfung beauftragten Behörde **Versuchsberichte** zugegangen, dürfen diese dem Verfahren vor dem EPA zugrunde gelegt werden.

6.2 Proceedings before the EPO as **elected Office** (PCT II) are to be based on the following documents:

the documents on which the international preliminary examination report is based, including its possible **annexes**
(Such annexes must always be filed)

unless replaced by the **amendments** enclosed.

Where necessary, clarifications must be submitted on a separate sheet!

If the EPO as International Preliminary Examining Authority has received **test reports,** these may be used as the basis of proceedings before the EPO.

6.2 La procédure devant l'OEB **agissant en qualité d'office élu** (PCT II) doit se fonder sur les pièces suivantes :

les pièces sur lesquelles se fonde le rapport d'examen préliminaire international, y compris ses **annexes** éventuelles
(De telles annexes sont toujours à joindre)

dans la mesure où elles ne sont pas remplacées par les **modifications** jointes.

Le cas échéant, des explications doivent être jointes sur une feuille additionnelle!

Si l'OEB, agissant en qualité d'administration chargée de l'examen préliminaire international, a reçu des **rapports d'essais,** ceux-ci peuvent constituer la base de la procédure devant l'OEB.

7. Übersetzungen Beigefügt sind die nachfolgend angekreuzten Übersetzungen in einer der Amtssprachen des EPA (Deutsch, Englisch, Französisch):	**7. Translations** Translations in one of the official languages of the EPO (English, French, German) are enclosed as crossed below:	**7. Traductions** Vous trouverez, ci-joint, les traductions cochées ci-après dans l'une des langues officielles de l'OEB (allemand, anglais, français) :
• *Im Verfahren vor dem EPA als* ***Bestimmungsamt oder ausgewähltem Amt*** *(PCT I + II):*	• *In proceedings before the EPO as* ***designated or elected Office*** *(PCT I + II):*	• *Dans la procédure devant l'OEB agissant en qualité d'****office désigné ou élu*** *(PCT I + II):*
☐ Übersetzung der **ursprünglich eingereichten internationalen Anmeldung** (Beschreibung, Ansprüche, etwaige Textbestandteile in den Zeichnungen), der veröffentlichten Zusammenfassung, und etwaiger Angaben über biologisches Material nach Regel 13bis.3 und 13bis.4 PCT	Translation of the **international application** (description, claims, any text in the drawings) as **originally filed**, of the abstract as published and of any indication under Rule 13bis.3 and 13bis.4 PCT regarding biological material	Traduction de la **demande internationale telle que déposée initialement** (description, revendications, textes figurant éventuellement dans les dessins), de l'abrégé publié, et de toutes indications visées aux règles 13bis.3 et 13bis.4 du PCT concernant le matériel biologique
☐ Übersetzung der **prioritätsbegründenden Anmeldung(en)**	Translation of **the priority application(s)**	Traduction de la (des) **demande(s) ouvrant le droit de priorité**
☐ Es wird hiermit erklärt, daß die internationale Anmeldung in ihrer ursprünglich eingereichten Fassung eine vollständige Übersetzung der früheren Anmeldung ist (Regel 38(5) EPÜ)	It is hereby declared that the international application as originally filed is a complete translation of the previous application (Rule 38(5) EPC)	Il est déclaré par la présente que la demande internationale telle que déposée initialement est une traduction intégrale de la demande antérieure (règle 38(5) CBE)
• ***Zusätzlich*** *im Verfahren vor dem EPA als* ***Bestimmungsamt*** *(PCT I):*	• ***In addition,*** *in proceedings before the EPO as* ***designated Office*** *(PCT I):*	• ***De plus,*** *dans la procédure devant l'OEB agissant en qualité d'****office désigné*** *(PCT I) :*
☐ Übersetzung der nach Art. 19 PCT **geänderten Ansprüche** nebst Erklärung, falls diese dem Verfahren vor dem EPA zugrunde gelegt werden sollen (siehe Feld 6)	Translation of **amended claims** and any statement under Art. 19 PCT, if the claims as amended are to form the basis for the proceedings before the EPO (see Section 6)	Traduction des **revendications modifiées** et de la déclaration faite conformément à l'article 19 du PCT, si la procédure devant l'OEB doit être fondée sur les revendications modifiées (voir la rubrique 6)
• ***Zusätzlich*** *im Verfahren vor dem EPA als* ***ausgewähltem Amt*** *(PCT II):*	• ***In addition,*** *in proceedings before the EPO as* ***elected Office*** *(PCT II):*	• ***De plus,*** *dans la procédure devant l'OEB agissant en qualité d'****office élu*** *(PCT II) :*
☐ Übersetzung der **Anlagen zum internationalen vorläufigen Prüfungsbericht**	Translation of any **annexes to the international preliminary examination report**	Traduction des **annexes du rapport d'examen préliminaire international**
☐ **8. Biologisches Material** Die Erfindung bezieht sich auf bzw. verwendet biologisches Material, das nach Regel 28 EPÜ hinterlegt worden ist.	**8. Biological material** The invention relates to and/or uses biological material deposited under Rule 28 EPC.	**8. Matière biologique** L'invention concerne et/ou utilise de la matière biologique, déposée conformément à la règle 28 CBE.
☐ Die **Angaben nach Regel 28(1)c) EPÜ** (falls noch nicht bekannt, die Hinterlegungsstelle und das (die) Bezugszeichen [Nummer, Symbole usw.] des Hinterlegers) sind in der internationalen Veröffentlichung oder in der gemäß Feld 7 eingereichten Übersetzung enthalten auf:	The **particulars referred to in Rule 28(1)(c) EPC** (if not yet known, the depository institution and the identification reference(s) [number, symbols etc.] of the depositor) are given in the international publication or in the translation submitted under Section 7 on:	Les **indications visées à la règle 28(1)c) CBE** (si non encore connues, l'autorité de dépôt et la (les) référence(s) d'identification [numéro ou symboles etc.] du déposant) figurent dans la publication internationale ou dans une traduction produite conformément à la rubrique 7 à la / aux:
Seite(n) / Zeile(n)	page(s) / line(s)	page(s) / ligne(s)
Die **Empfangsbescheinigung(en)** der Hinterlegungsstelle	The **receipt(s) of deposit** issued by the depositary institution	Le(s) **récépissé(s) de dépôt** délivré(s) par l'autorité de dépôt
☐ ist (sind) beigefügt	is (are) enclosed	est (sont) joint(s)
☐ wird (werden) nachgereicht	will be filed at a later date	sera (seront) produit(s) ultérieurement
☐ Verzicht auf die Verpflichtung des Antragstellers nach Regel 28(3) EPÜ auf gesondertem Schriftstück	Waiver of the right to an undertaking from the requester pursuant to Rule 28(3) EPC attached.	Renonciation, sur document distinct, à l'engagement du requérant au titre de la règle 28(3) CBE.

9. Nucleotid- und Aminosäuresequenzen

☐ Die nach Regeln 5.2 und 13ter PCT sowie Regel 111(3) EPÜ erforderlichen Unterlagen liegen dem EPA bereits vor.

☐ Das schriftliche Sequenzprotokoll wird anliegend nachgereicht.

☐ Das Sequenzprotokoll geht nicht über den Inhalt der Anmeldung in der ursprünglich eingereichten Fassung hinaus.

☐ Der vorgeschriebene Datenträger ist beigefügt.

☐ Die auf dem Datenträger gespeicherte Information stimmt mit dem schriftlichen Sequenzprotokoll überein.

9. Nucleotide and amino acid sequences

The items necessary in accordance with Rules 5.2 and 13ter PCT and Rule 111(3) EPC have already been furnished to the EPO.

The written sequence listing is furnished herewith.

The sequence listing does not include matter which goes beyond the content of the application as filed.

The prescribed data carrier is enclosed.

The information recorded on the data carrier is identical to the written sequence listing.

9. Séquences de nucléotides et d'acides aminés

Les pièces requises selon les règles 5.2 et 13ter PCT et la règle 111(3) CBE ont déjà été déposées auprès de l'OEB.

La liste de séquences écrite est produite ci-joint.

La liste de séquences ne contient pas d'éléments s'étendant au-delà du contenu de la demande telle qu'elle a été déposée.

Le support de données prescrit est joint.

L'information figurant sur le support de données est identique à celle que contient la liste de séquences écrite.

10. Benennungsgebühren

☒ 10.1 Es ist derzeit beabsichtigt, den **siebenfachen** Betrag einer Benennungsgebühr zu entrichten. Damit gelten die Benennungsgebühren für **alle Vertragsstaaten des EPÜ**[1] als entrichtet (Art. 2 Nr. 3 GebO), soweit sie **in der Internationalen Anmeldung** bestimmt sind[2].

☐ 10.2 Abweichend von der Erklärung in Nr. 10.1 ist derzeit beabsichtigt, **weniger als sieben** Benennungsgebühren für folgende **in der internationalen Anmeldung bestimmte Vertragsstaaten des EPÜ**[2] zu entrichten:

(1) ☐ _____
(2) ☐ _____
(3) ☐ _____

Soweit unter Nr. 10.2 Vertragsstaaten aufgeführt sind, wird beantragt, für die dort nicht aufgeführten Vertragsstaaten von der Zustellung einer Mitteilung nach Regel 108(3) EPÜ abzusehen.

☒ 10.3 Wird ein **automatischer Abbuchungsauftrag** erteilt (Feld 12), so wird das EPA beauftragt, bei Ablauf der Grundfrist nach Regel 107 (1)d) EPÜ den siebenfachen Betrag einer Benennungsgebühr abzubuchen. Ist eine Erklärung nach Nr. 10.2 abgegeben worden, so sollen die Benennungsgebühren nur für die dort angegebenen Vertragsstaaten abgebucht werden, sofern dem EPA nicht bis zum Ablauf der Grundfrist ein anderslautender Auftrag zugeht.

10. Designation fees

10.1 It is currently intended to pay **seven times** the amount of the designation fee. The designation fees for **all the EPC contracting states**[1] **designated in the international application**[2] are thereby deemed to have been paid (Art. 2 No. 3 RFees).

10.2 The declaration in No. 10.1 does not apply. Instead, it is currently intended to pay **fewer than seven** designation fees for the following **EPC contracting states**[2] **designated in the international application**:

(4) ☐ _____
(5) ☐ _____
(6) ☐ _____

If contracting states are indicated under No. 10.2, it is requested that no communication under Rule 108(3) EPC be issued for contracting states not thus indicated.

10.3 If an **automatic debit order** has been issued (Section 12), the EPO is authorised, on expiry of the basic period under Rule 107(1)(d) EPC, to debit seven times the amount of the designation fee. If states are indicated under No. 10.2, the EPO will debit designation fees only for those states, unless instructed otherwise before the basic period expires.

10. Taxes de désignation

10.1 Il est actuellement envisagé de payer un montant correspondant à **sept fois** la taxe de désignation. Les taxes de désignation sont ainsi réputées payées pour **tous les Etats contractants de la CBE**[1] **désignés dans la demande internationale**[2] (art. 2, point 3 du RRT).

10.2 Contrairement à ce qui est indiqué au n° 10.1, il est actuellement envisagé de payer **moins de sept** taxes de désignation pour les **Etats contractants de la CBE**[2] suivants **désignés dans la demande internationale** :

(4) ☐ _____
(5) ☐ _____
(6) ☐ _____

Si des Etats contractants sont mentionnés au n° 10.2, prière de ne pas procéder à la signification d'une notification prévue par la règle 108(3) CBE pour les Etats contractants n'y étant pas mentionnés.

10.3 Si un **ordre de prélèvement automatique** est donné (rubrique 12), il est demandé à l'OEB de prélever, à l'expiration du délai normal visé à la règle 107(1)d) CBE, un montant correspondant à sept fois la taxe de désignation. Si une déclaration a été faite au n° 10.2, les taxes de désignation ne sont à prélever que pour les Etats contractants qui y sont indiqués, sauf instruction contraire reçue par l'OEB avant l'expiration du délai normal.

1 Stand bei Drucklegung: 27 Vertragsstaaten, und zwar: / Status when this form was printed: 27 contracting states, namely / Situation à la date d'impression : 27 Etats contractants, à savoir : AT Österreich / Austria / Autriche, BE Belgien / Belgium / Belgique, BG Bulgarien / Bulgaria / Bulgarie, CH / LI Schweiz und Liechtenstein / Switzerland and Liechtenstein / Suisse et Liechtenstein, CY Zypern / Cyprus / Chypre, CZ Tschechische Republik / Czech Republic / République tchèque, DE Deutschland / Germany / Allemagne, DK Dänemark / Denmark / Danemark, EE Estland / Estonia / Estonie, ES Spanien / Spain / Espagne, FI Finnland / Finland / Finlande, FR Frankreich / France / France, GB Vereinigtes Königreich / United Kingdom / Royaume-Uni, GR Griechenland / Greece / Grèce, HU Ungarn / Hungary / Hongrie, IE Irland / Ireland / Irlande, IT Italien / Italy / Italie, LU Luxemburg / Luxembourg / Luxembourg, MC Monaco / Monaco / Monaco, NL Niederlande / Netherlands / Pays-Bas, PT Portugal / Portugal / Portugal, RO Rumänien / Romania / Roumanie, SE Schweden / Sweden / Suède, SI Slowenien / Slovenia / Slovénie, SK Slowakische Republik / Slovak Republic / République slovaque, TR Türkei / Turkey / Turquie

2 Für folgende Staaten nur möglich, falls in der internationalen Anmeldung am oder nach folgendem Tag bestimmt: Slowakische Republik, Bulgarien, Tschechische Republik und Estland: 1. Juli 2002, Slowenien: 1. Dezember 2002, Ungarn: 1. Januar 2003 und Rumänien: 1. März 2003. / For the following states this is possible only if they are designated in the international application on or after the stated date: Slovak Republic, Bulgaria, Czech Republic and Estonia: 1 July 2002, Slovenia: 1 December 2002, Hungary: 1 January 2003 and Romania: 1 March 2003. / En ce qui concerne les Etats suivants seulement si la désignation a été effectuée dans la demande internationale à la date suivante ou à une date ultérieure: République slovaque, Bulgarie, République tchèque et Estonie: 1er juillet 2002, Slovénie: 1er décembre 2002, Hongrie: 1er janvier 2003 et Roumanie: 1er mars 2003.

☒	**11. Erstreckung des europäischen Patents** Bei Zahlung der Erstreckungsgebühr(en) gilt diese Anmeldung auch als wirksamer Erstreckungsantrag für die in der internationalen Anmeldung bestimmten »Erstreckungsstaaten«. Es ist beabsichtigt, diese Gebühr(en) für folgende Staaten zu entrichten:	**11. Extension of the European patent** On payment of the extension fee(s) this application is also deemed to be a request for extension to all the "extension states" designated in the international application. It is intended to pay the fee(s) for the following states:	**11. Extension des effets du brevet européen** La taxe (Les taxes) d'extension payée(s), la présente demande est également réputée être une demande d'extension à tous les «États autorisant l'extension» désignés dans la demande internationale. Il est envisagé de payer la taxe (les taxes) d'extension pour les États suivants:		
☐	SI	Slowenien [1]	Slovenia [1]	Slovénie [1]	
☐	LT	Litauen	Lithuania	Lituanie	
☒	LV	Lettland	Latvia	Lettonie	
☒	AL	Albanien	Albania	Albanie	
☐	RO	Rumänien [1]	Romania [1]	Roumanie [1]	
☒	MK	Ehemalige jugoslawische Republik Mazedonien	Former Yugoslav Republic of Macedonia	Ex-République yougoslave de Macédoine	
☒	HR	Croatia [2]	BA Bosnia & Herzegovina [2]	YU Serbia & Montenegro [2]	

1) Für Slowenien und Rumänien nur möglich, falls in der internationalen Anmeldung bis 30. November 2002 (Slowenien) oder bis 28. Februar 2003 (Rumänien) bestimmt / For Slovenia and Romania this is possible only if they are designated in the international application up to 30 November 2002 (Slovenia) or 28 February 2003 (Romania). / En ce qui concerne la Slovénie et la Roumanie, seulement si la désignation a été effectuée dans la demande internationale jusqu'au 30 novembre 2002 (Slovénie) ou jusqu'au 28 février 2003 (Roumanie).

2) Platz für Staaten, mit denen »Erstreckungsabkommen« nach Drucklegung dieses Formblatts in Kraft treten und die in der internationalen Anmeldung bestimmt waren. / Space for States with which "extension agreements" enter into force after this form has been printed and which were designated in the international application. / Prévu pour des États à l'égard desquels des «accords d'extension» entreront en vigueur après l'impression du présent formulaire et qui ont été désignés dans la demande internationale.

☐	**12. Automatischer Abbuchungsauftrag** ***(Nur möglich für Inhaber von beim EPA geführten laufenden Konten)*** Das EPA wird beauftragt, nach Maßgabe der Vorschriften über das automatische Abbuchungsverfahren fällige Gebühren und Auslagen vom untenstehenden laufenden Konto abzubuchen. In Bezug auf die **Benennungsgebühren** wird auf Feld 10.3 verwiesen. Das EPA wird ferner beauftragt, die **Erstreckungsgebühren** für jeden in Feld 11 angekreuzten »Erstreckungsstaat« bei Ablauf der Grundfrist zu ihrer Zahlung abzubuchen, sofern ihm nicht bis dahin ein anderslautender Auftrag zugeht. Nummer und Kontoinhaber	**12. Automatic debit order** ***(for EPO deposit account holders only)*** The EPO is hereby authorised, under the Arrangements for the automatic debiting procedure, to debit from the deposit account below any fees and costs falling due. For **designation fees**, see Section 10.3. The EPO is also authorised, on expiry of the basic period for paying the **extension fees**, to debit those fees for each of the "extension states" marked with a cross in Section 11, unless instructed otherwise before the said period expires. Number and account holder	**12. Ordre de prélèvement automatique** ***(uniquement possible pour les titulaires de comptes courants ouverts auprès de l'OEB)*** Par la présente, il est demandé à l'OEB de prélever du compte courant ci-dessous les taxes et frais venant à échéance, conformément à la réglementation relative au prélèvement automatique. Pour les **taxes de désignation**, se reporter à la rubrique 10.3. Il est en outre demandé à l'OEB de prélever, à l'expiration du délai normal prévu pour leur paiement, les **taxes d'extension** pour chaque «Etat autorisant l'extension» coché à la rubrique 11, sauf instruction contraire reçue avant l'expiration de ce délai. Numéro et titulaire du compte
☒	**13.** Eventuelle **Rückzahlungen** auf das beim EPA geführte laufende Konto Nummer und Kontoinhaber	**13.** Any **reimbursement** to EPO deposit account Number and account holder Harrison Goddard Foote - 28050228	**13. Remboursements** éventuels à effectuer sur le compte courant ouvert auprès de l'OEB Numéro et titulaire du compte
	14. Unterschrift(en) des (der) Anmelder(s) oder Vertreters **Ort / Datum** **Für Angestellte (Art. 133(3) EPÜ) mit allgemeiner Vollmacht:** **Nr.** Name(n) des (der) Unterzeichneten bitte in Druckschrift wiederholen. Bei juristischen Personen bitte auch die Stellung des (der) Unterzeichneten innerhalb der Gesellschaft in Druckschrift angeben.	**14. Signature(s)** of applicant(s) or representative STAINTHORPE, Vanessa Juliet **Place / Date** 22.08.2006, Sheffield, UK **For employees (Art. 133(3) EPC) having a general authorisation:** **No.** Please print name(s) under signature(s). In the case of legal persons, the position of the signatory within the company should also be printed.	**14. Signature(s)** du (des) demandeur(s) ou du mandataire **Lieu / Date** **Pour les employés (art. 133(3) CBE) disposant d'un pouvoir général :** **N°** Le ou les noms des signataires doivent être indiqués en caractères d'imprimerie. S'il s'agit d'une personne morale, la position occupée au sein de celle-ci par le ou les signataires doit également être indiquée en caractères d'imprimerie.

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the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing inside which is located

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing is in communication with both the plunger and the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which the inner housing is in communication with neither the plunger nor the barrel

a plunger, axially moveable within the barrel, wherein the injection device further comprises:

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

characterised in that the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

31. An injection device as claimed in claim 29 or claim 30 having all of the features of any of claims 2-28.

the plunger.

An alternative way of concealing the needle after an injection has been delivered is described in US6544234 (BD Medico SARL), which discloses an injection device in which the needle is concealed before injection, but the configuration of the device is such that the needle cannot retract after injection. Instead, there is a moveable needle protection sleeve which is displaced by a compression spring when the needle is pulled out of the subcutaneous tissue in order to conceal the needle from the patient.

Although the present invention may relate to mini-needle or jet injection devices, the invention is equally applicable to other types of injection device, for example those for deep-penetrating muscular injection as well as those which are for shallower, subcutaneous, injection.

According to a first aspect of the present invention there is provided an injection device comprising an outer housing inside which is located

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source between three positions, namely

a plunger, axially moveable within the barrel, wherein the injection device further comprises:

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

characterised in that the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

31. An injection device as claimed in claim 29 or claim 30 having all of the features of any of claims 2-28.

~~32. An injection device substantially as described herein with reference to and as illustrated in any appropriate combination of the accompanying drawings.~~